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**
2850	KADSURA COCCINEA	A, H	
2851	KAEMPFERIA GALANGA	A, H	
2852	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%.
2853	KAOLIN	E	
2854	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.
2855	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.
2856	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%.
2857	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%.
2858	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'.
2859	KIDNEY BEAN	E	
2860	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%.
2861	KIWI FRUIT	E	
2862	KNAUTIA ARVENSIS	A, H	
2863	KOREAN GINSENG ROOT DRY	A, H	
2864	KOREAN GINSENG ROOT POWDER	A, H	
2865	KRAMERIA IXINE	A, H	
2866	KRAMERIA LAPPACEA	A, H	
2867	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

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			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'.
2868	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%.
2869	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%.
2870	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%.
2871	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.
2872	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%.
2873	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%.
2874	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%.
2875	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%.
2876	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%.
2877	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%.
2878	LABDANUM OIL	A, E, H	
2879	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%.
2880	LACTALBUMIN	E	

2881	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.
2882	LACTITOL	E	
2883	LACTITOL MONOHYDRATE	E	
2884	LACTO-N-NEOTETRAOSE	A	Lactose is a mandatory component of lacto-N-neotetraose. The route of administration for medicines that contain lacto-N-neotetraose must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than: (a) 1.5 g of lacto-N-neotetraose to individuals aged 4 years and older; and (b) 0.6 g of lacto-N-neotetraose to individuals aged up to 3 years (inclusive). One of the following statements (or words to the same effect) is required on the medicine label: (a) When the medicine is only for use in individuals aged 2 years and above: ‘Not to be taken on the same day with other products containing lacto-N-neotetraose'; or (b) When the medicine is for use in children aged less than 2 years:

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			‘Not to be taken on the same day with breastmilk or other products containing lacto-N-neotetraose’.
2885	LACTO-N-TETRAOSE	A	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 the same effect) is required on the medicine label: a) When the medicine is only for use in individuals aged 2 years and above: 'Not to be taken on the same day with other products containing lacto-N-tetraose'; or b) When the medicine is for use in children aged less than 2 years: 'Not to be taken on the same day with breastmilk or other products containing lacto-N-tetraose'.
2886	LACTOBACILLUS ACIDOPHILUS	A	
2887	LACTOBACILLUS AMYLOVORUS	A	
2888	LACTOBACILLUS BREVIS	A	
2889	LACTOBACILLUS CASEI	A	
2890	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	

2891	LACTOBACILLUS CRISPATUS	A	
2892	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2893	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2894	LACTOBACILLUS FERMENTUM	A	
2895	LACTOBACILLUS GALLINARUM	A	
2896	LACTOBACILLUS GASSERI	A	
2897	LACTOBACILLUS HELVETICUS	A	
2898	LACTOBACILLUS JOHNSONII	A	
2899	LACTOBACILLUS KEFIRANOFACIENS	A	
2900	LACTOBACILLUS KEFIRGRANUM	A	
2901	LACTOBACILLUS KEFIRI	A	
2902	LACTOBACILLUS PARACASEI	A	
2903	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2904	LACTOBACILLUS PLANTARUM	A	
2905	LACTOBACILLUS REUTERI	A	
2906	LACTOBACILLUS RHAMNOSUS	A	
2907	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2908	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2909	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2910	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%.
2911	LACTOSE	E	
2912	LACTOSE MONOHYDRATE	E	
2913	LACTUCA SATIVA	A, H	

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2914	LACTUCA VIROSA	A, H	
2915	LACTULOSE	E	
2916	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.
2917	LAGENARIA VULGARIS	A, H	
2918	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.
2919	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.
2920	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.
2921	LAMIUM ALBUM	A, H	
2922	LANETH-5	E	Only for use in topical medicines for dermal application.
2923	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2924	LANOLIN OIL	E	Only for use in topical medicines for dermal application.
2925	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2926	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.
2927	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

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			arabinogalactan in topical medicines for dermal application must not exceed 5.0%.
2928	LARIX DECIDUA	A, H	
2929	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.
2930	LARREA TRIDENTATA	A, H	The following warning statement is required on the medicine label: (CHAP1) 'In rare cases, Larrea tridentata may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain or dark urine.'
2931	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.
2932	LAURAMINE OXIDE	E	
2933	LAUREL LEAF OIL	A, H	When the total concentration of bay oil in the medicine is more than 25%: (a) the nominal capacity of the container must not be more than 25 mL; (b) the container must be fitted with a restricted flow insert; (c) the following warning statements are required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and (d) when the nominal capacity of

			the container is greater than 15 mL, the container must also be fitted with a child resistant closure.
2934	LAURETH-10	E	Only for use in topical medicines for dermal application.
2935	LAURETH-12	E	Only for use in topical medicines for dermal application.
2936	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.
2937	LAURETH-23	E	Only for use in topical medicines for dermal application.
2938	LAURETH-3	E	Only for use in topical medicines for dermal application.
2939	LAURETH-4	E	Only for use in topical medicines for dermal application.
2940	LAURETH-7	E	Only for use in topical medicines for dermal application.
2941	LAURETH-8	E	
2942	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.
2943	LAURIL MACROGOL 400 DIMETICONE	E	Only for use in topical medicines for dermal application and not to

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			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%.
2944	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2945	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%.
2946	LAURUS NOBILIS	A, E, H	When the plant preparation is oil or distillate, and the concentration of bay oil or distillate in the medicine is greater than 25%: (a) the nominal capacity of the container must not be more than 25 mL; (b) the container must be fitted with a restricted flow insert; (c) the following warning statements are required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and (d) when the nominal capacity of the container is greater than 15 mL, the container must also be fitted with a child resistant closure.
2947	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%.
2948	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2949	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%.
2950	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.
2951	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%.
2952	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.

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			The concentration in the medicine must be no more than 2%.
2953	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%.
2954	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.
2955	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.
2956	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2957	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2958	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%.

2959	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2960	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%.
2961	LAVANDIN OIL ABRIAL	A, E, H	
2962	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%.
2963	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%.
2964	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%.

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			In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.
2965	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%.
2966	LAVENDER OIL	A, E, H	
2967	LAWSONIA INERMIS	A, H	
2968	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2969	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.
2970	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%.
2971	LECITHIN	A, E	
2972	LEDEBOURIELLA SESELOIDES	A, H	
2973	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.
2974	LEMNA MINOR	A, H	
2975	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.
2976	LEMON BALM LEAF DRY	A, H	
2977	LEMON BALM LEAF POWDER	A, E, H	
2978	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

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			oil; or d) for use in soaps or bath or shower gels that are washed off the skin.
2979	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.
2980	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.
2981	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%.
2982	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.
2983	LEMONGRASS OIL	A, E, H	
2984	LENS CULINARIS	A, H	

2985	LENTIL	E	
2986	LENTINULA EDODES	A, E, H	
2987	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%.
2988	LEONURUS CARDIACA	A, E, H	
2989	LEONURUS SIBIRICUS	A, E, H	
2990	LEPIDIUM APETALUM	A, H	
2991	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).
2992	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.
2993	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’
2994	LESPEDEZA CAPITATA	A, H	
2995	LETTUCE	E	
2996	LEUCINE	A, E	
2997	LEUZEA UNIFLORA	A, H	
2998	LEVISTICUM OFFICINALE	A, H	
2999	LEVOCARNITINE	A	
3000	LEVOCARNITINE FUMARATE	A	
3001	LEVOCARNITINE HYDROCHLORIDE	A	
3002	LEVOCARNITINE MAGNESIUM CITRATE	A	
3003	LEVOCARNITINE TARTRATE	A	
3004	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.
3005	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.
3006	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
3007	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%.
3008	LIGHT KAOLIN	E	
3009	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.
3010	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.
3011	LIGUSTICUM SINENSE	A, H	
3012	LIGUSTICUM STRIATUM	A, E, H	
3013	LIGUSTRUM LUCIDUM	A, H	
3014	LILIUM BROWNII	A, H	

3015	LILIUM CANDIDUM	A, E, H	
3016	LILIUM LANCIFOLIUM	A, H	
3017	LILIUM LONGIFLORUM	A, H	
3018	LIME FRUIT	E	
3019	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%.
3020	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.
3021	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.
3022	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%.
3023	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%.
3024	LIME TREE FLOWER DRY	A, H	
3025	LIME TREE FLOWER POWDER	A, H	
3026	LIME, ESSENCE	E	
3027	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%.
3028	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.
3029	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%.
3030	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%.
3031	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%.
3032	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%.
3033	LINALYL BENZOATE	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%.
3034	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%.
3035	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%.
3036	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%.
3037	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%.

3038	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%.
3039	LINDERA STRYCHNIFOLIA	A, H	
3040	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%.
3041	LINOLEIC ACID	E	
3042	LINOLENIC ACID	E	
3043	LINSEED DRY	A, E, H	
3044	LINSEED OIL	A, E, H	
3045	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.
3046	LINSEED POWDER	A, E, H	
3047	LINUM USITATISSIMUM	A, E, H	
3048	LIPASE	A	Permitted for use only when derived from Rhizopus oryzae and in medicines containing 20,000 lipase units (equivalent to 20,000

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			BP units) or less of lipase activity per dosage unit. Lipase must comply with the relevant compositional guideline.
3049	LIPPIA DULCIS	A, H	
3050	LIQUID GLUCOSE	E	
3051	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.
3052	LIQUIDAMBAR FORMOSANA	A, H	
3053	LIQUIDAMBAR ORIENTALIS	A, H	
3054	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3055	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%.
3056	LIQUIDAMBAR TAIWANIANA	A, H	
3057	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%.
3058	LIQUORICE DRY	A, E, H	
3059	LIQUORICE LIQUID EXTRACT	A, E, H	
3060	LIQUORICE POWDER	A, E, H	
3061	LITCHI CHINENSIS	A, H	
3062	LITHIUM CARBONATE	H	Only for use as an active

			homoeopathic ingredient.
3063	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
3064	LITSEA CUBEBA	A, E, H	
3065	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%.
3066	LOBARIA PULMONARIA	A, H	
3067	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.
3068	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.
3069	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.
3070	LOLIUM PERENNE	A, H	
3071	LOLIUM TEMULENTUM	A, H	
3072	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%.
3073	LONICERA CAPRIFOLIUM	A, E, H	
3074	LONICERA JAPONICA	A, E, H	
3075	LONICERA PERICLYMENUM	A, H	
3076	LOPHATHERUM GRACILE	A, H	
3077	LOQUAT	E	
3078	LORANTHUS PARASITICUS	A, H	
3079	LOROPETALUM CHINENSE	A, H	
3080	LOTUS CORNICULATUS	A, H	
3081	LOVAGE OIL	A, E, H	
3082	LOVAGE ROOT DRY	A, H	
3083	LOVAGE ROOT POWDER	A, H	
3084	LUDWIGIA PROSTRATA	A, H	
3085	LUFFA CYLINDRICA	A, H	
3086	LUFFA PURGANS	A, H	
3087	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.
3088	LYCHEE	E	
3089	LYCIUM BARBARUM	A, H	
3090	LYCIUM CHINENSE	A, E, H	
3091	LYCOPENE	A, E	
3092	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.
3093	LYCOPODIUM ANNOTINUM	A, H	

3094	LYCOPODIUM CLAVATUM	A, H	
3095	LYCOPODIUM COMPLANATUM	A, H	
3096	LYCOPUS EUROPAEUS	A, H	
3097	LYCOPUS LUCIDUS	A, H	
3098	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%.
3099	LYGODIUM JAPONICUM	A, H	
3100	LYSIMACHIA CHRISTINAE	A, H	
3101	LYSIMACHIA VULGARIS	A, H	
3102	LYSINE	A, E	
3103	LYSINE HYDROCHLORIDE	A, E	
3104	LYTHRUM HYSSOPIFOLIA	A, H	
3105	LYTHRUM SALICARIA	A, H	
3106	LYTHRUM VERTICILLATUM	A, H	
3107	MACADAMIA INTEGRIFOLIA	A, E	
3108	MACADAMIA NUT OIL	E	
3109	MACADAMIA TERNIFOLIA	A, E, H	
3110	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%.
3111	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

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			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.
3112	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.
3113	MACROGOL 1000	E	
3114	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3115	MACROGOL 1500	E	
3116	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%.
3117	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3118	MACROGOL 20000	E	
3119	MACROGOL 300	E	
3120	MACROGOL 3000	E	
3121	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.
3122	MACROGOL 40	E	Only for use in topical medicines for dermal application.
3123	MACROGOL 400	E	
3124	MACROGOL 4000	E	
3125	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3126	MACROGOL 600	E	
3127	MACROGOL 6000	E	
3128	MACROGOL 600000	E	
3129	MACROGOL 800	E	
3130	MACROGOL 8000	E	
3131	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%.
3132	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3133	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3134	MAGNESIUM AMINO ACID CHELATE	A, E, H	Only for use in oral medicines. The concentration of magnesium must be no more than 25% of the magnesium amino acid chelate.
3135	MAGNESIUM ASCORBATE	A, E, H	
3136	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	

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3137	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3138	MAGNESIUM ASPARTATE	A, E, H	
3139	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3140	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3141	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3142	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.

3143	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.
3144	MAGNESIUM CITRATE	A, E, H	
3145	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	
3146	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	
3147	MAGNESIUM DIGLUTAMATE	A, E, H	
3148	MAGNESIUM GLUCONATE	A, E, H	
3149	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3150	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.

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3151	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.
3152	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.

3153	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.
3154	MAGNESIUM LYSINATE	A	Only for use in oral medicines.

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3155	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3156	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3157	MAGNESIUM OROTATE	A, E, H	
3158	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3159	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.
3160	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.
3161	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.
3162	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.
3163	MAGNESIUM STEARATE	E	
3164	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.
3165	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.
3166	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.
3167	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.
3168	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.
3169	MAGNOLIA GLAUCA	A, H	
3170	MAGNOLIA LILIFLORA	A, H	
3171	MAGNOLIA OBOVATA	A, H	
3172	MAGNOLIA OFFICINALIS	A, E, H	
3173	MAGNOLIA SALICIFOLIA	A, H	
3174	MAIZE OIL	A, E, H	
3175	MAIZE STARCH	A, E, H	

3176	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3177	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.
3178	MALPIGHIA GLABRA	A, E, H	
3179	MALT EXTRACT	E	
3180	MALTITOL	E	
3181	MALTITOL SOLUTION	E	
3182	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.
3183	MALTOL	E	
3184	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%.
3185	MALTOSE	E	
3186	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
3187	MALUS SYLVESTRIS	A, H	
3188	MALVA MOSCHATA	A, H	
3189	MALVA SYLVESTRIS	A, E, H	
3190	MALVA VERTICILLATA	A, H	
3191	MANDARIN	E	
3192	MANDARIN OIL	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%.
3193	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.
3194	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%.
3195	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%.
3196	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%.
3197	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3198	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3199	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3200	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3201	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.
3202	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3203	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.
3204	MANGANESE GLUCONATE	A, E, H	
3205	MANGANESE GLYCEROPHOSPHATE	A, E, H	
3206	MANGANESE OXIDE	A, E, H	
3207	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3208	MANGANESE SULFATE TETRAHYDRATE	A, E, H	

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3209	MANGIFERA INDICA	A, E, H	
3210	MANGO	E, H	
3211	MANIHOT ESCULENTA	A, H	
3212	MANNITOL	E	
3213	MARANTA ARUNDINACEA	A, H	
3214	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3215	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).
3216	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).
3217	MARRUBIUM VULGARE	A, E, H	
3218	MARSDENIA CUNDURANGO	A, H	
3219	MARSHMALLOW ROOT DRY	A, H	
3220	MARSHMALLOW ROOT POWDER	A, H	
3221	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%.
3222	MASTIC	A, H	
3223	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%.
3224	MATRICARIA CHAMOMILLA	A, E, H	
3225	MATRICARIA FLOWER DRY	A, E, H	
3226	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 warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
3227	MECOBALAMIN	A	Only for use in oral medicines.
3228	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.
3229	MEDIUM CHAIN TRIGLYCERIDES	E	
3230	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.
3231	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.
3232	MELALEUCA CITRINA	A, H	
3233	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.
3234	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.
3235	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.
3236	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.
3237	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.
3238	MELICOPE PTELEIFOLIA	A, H	
3239	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%.
3240	MELISSA OFFICINALIS	A, E, H	
3241	MELON	E	
3242	MENADIONE SODIUM BISULFITE	E	
3243	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.
3244	MENISPERMUM CANADENSE	A, H	
3245	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.
3246	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.

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3247	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 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 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.
3249	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.
3250	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

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	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.

3251	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.
3252	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.
3253	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.
3254	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.
3255	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%.
3256	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%.
3257	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 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.
3258	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%.
3259	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%.
3260	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%.
3261	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3262	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%.
3263	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%.
3264	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: - (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).
3265	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%.
3266	MENTHYL LACTATE	E	
3267	MENYANTHES TRIFOLIATA	A, H	
3268	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%.
3269	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%.
3270	METACRESOL	E	Only for use in topical medicines for dermal application.
3271	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3272	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%.
3273	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%.
3274	METHIONINE	A, E	

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3275	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%.
3276	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%.
3277	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%.
3278	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%.
3279	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%.
3280	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%.
3281	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3282	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%.
3283	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%.
3284	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3285	METHYL BUTYRATE	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%.
3286	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%.
3287	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%.
3288	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%.
3289	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%.
3290	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%.
3291	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%.
3292	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%.
3293	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%.

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3294	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%.
3295	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%.
3296	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%.
3297	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%.
3298	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3299	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%.
3300	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%.
3301	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%.
3302	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.
3303	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.
3304	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%.
3305	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3306	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines

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			for dermal application.
3307	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3308	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3309	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%.
3310	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%.
3311	METHYL HEPTYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3312	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%.
3313	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%.
3314	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3315	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3316	METHYL HYDROXYBENZOATE	E	
3317	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%.
3318	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%.
3319	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%.
3320	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%.
3321	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%.
3322	METHYL LAURATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
3323	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%.
3324	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%.
3325	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%.
3326	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%.
3327	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%.

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3328	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%.
3329	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%.
3330	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%.
3331	METHYL NONYLENATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3332	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%.
3333	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%.
3334	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%.
3335	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%.
3336	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%.
3337	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%.
3338	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%.
3339	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%.
3340	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,

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			discontinue use'.
3341	METHYL STEARATE	E	
3342	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%.
3343	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%.
3344	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%.
3345	METHYL-BETA-METHYL THIOLPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3346	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%.
3347	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%.
3348	METHYLCELLULOSE	A, E	
3349	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%.
3350	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%.
3351	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).

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3352	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%.
3353	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%.
3354	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%.
3355	METHYLSILANOL/SILICATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
3356	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3357	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%.
3358	MICROCALICIUM ARENARIUM	A, H	
3359	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%.
3360	MICROCOS PANICULATA	A, H	
3361	MICROCRYSTALLINE CELLULOSE	E	
3362	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'.
3363	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%.
3364	MILK THISTLE FRUIT DRY	A, H	
3365	MILK THISTLE FRUIT POWDER	A, H	
3366	MILLET	E	
3367	MILLETTIA DIELSIANA	A, H	
3368	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%.

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3369	MIMULUS GUTTATUS	A, H	
3370	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, 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.

3371	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%.
3372	MITCHELLA REPENS	A, H	
3373	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3374	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3375	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%.
3376	MODIFIED FOOD STARCH	E	
3377	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%.
3378	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.

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3379	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.
3380	MOMORDICA BALSAMINA	A, H	
3381	MOMORDICA CHARANTIA	A, H	
3382	MOMORDICA COCHINCHINENSIS	A, H	
3383	MONARDA DIDYMA	A, H	
3384	MONO- AND DI- GLYCERIDES	E	
3385	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3386	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3387	MONOBASIC POTASSIUM PHOSPHATE	A, E, H	When used in a solid medicine containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid medicine containing this ingredient, the pH of the medicine must be no more than 11.5.
3388	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.
3389	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.
3390	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3391	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.
3392	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.
3393	MONOPHOSPHOTHIAMINE	A	
3394	MONOPHOSPHOTHIAMINE DIHYDRATE	A	
3395	MONOPOTASSIUM GLUTAMATE	A, E	

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3396	MONOSODIUM DIHYDROGEN CITRATE	E	
3397	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	
3398	MONSTERA DELICIOSA	A, H	
3399	MONTAN WAX	E	
3400	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%..
3401	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).
3402	MORINDA OFFICINALIS	A, H	
3403	MORINGA OLEIFERA	A, H	
3404	MORUS ALBA	A, H	
3405	MORUS BOMBYCIS	A, H	
3406	MORUS NIGRA	A, E, H	
3407	MOSKENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3408	MOTHERWORT HERB DRY	A, H	
3409	MOTHERWORT HERB POWDER	A, H	
3410	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%.
3411	MULBERRY	E	

3412	MUNG BEAN	E	
3413	MURRAYA KOENIGII	A, H	
3414	MURRAYA PANICULATA	A, H	
3415	MUSA X PARADISIACA	A, H	
3416	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3417	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%.
3418	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3419	MUSKS	H	Only for use as an active homoeopathic ingredient.
3420	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%.
3421	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%.
3422	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%.
3423	MYOSOTIS ARVENSIS	A, H	
3424	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%.
3425	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%.
3426	MYRICA CERIFERA	A, E, H	
3427	MYRISTIC ACID	E	
3428	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%.
3429	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).
3430	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3431	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3432	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3433	MYROXYLON BALSAMUM	A, E, H	
3434	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3435	MYRRH	A, H	
3436	MYRRH OIL	A, E, H	
3437	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3438	MYRRHIS ODORATA	A, H	
3439	MYRSINE AFRICANA	A, H	
3440	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%.
3441	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%.
3442	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%.
3443	MYRTUS COMMUNIS	A, E, H	
3444	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.
3445	N-(2-(PYRIDIN-2-YL)ETHYL)-P-	E	N-(2-(pyridin-2-yl)ethyl)-p-

	MENTHANE-3-CARBOXAMIDE		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.
3446	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%.
3447	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%.
3448	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

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			5%.
3449	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%.
3450	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3451	NARDOSTACHYS CHINENSIS	A, H	
3452	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%.
3453	NASTURTIUM OFFICINALE	A, E, H	
3454	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.
3455	NAUCLEA OFFICINALIS	A, H	
3456	NELUMBO NUCIFERA	A, H	
3457	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%.
3458	NEOHESPERIDIN-DIHYDROCHALCONE	E	The routes of administration for medicines that contain

			neohesperidin-dihydrochalcone must be limited to: (a) topical for dermal application; and (b) oral. When used in topical medicines for dermal application: (a) neohesperidin-dihydrochalcone must not be included in medicines intended for use in the eye or on damaged skin; and (b) the concentration of neohesperidin-dihydrochalcone in the medicine must not be more than 0.1%. When used in oral medicines: (a) the concentration in the medicine must not be more than 0.1%; and (b) the following warning statement (or words to that effect) is required on the medicine label: - (NTAKEN3) 'Not to be taken by children under 3 years old'.
3459	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%.
3460	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%.
3461	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%.
3462	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.
3463	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3464	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3465	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%.
3466	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%.
3467	NERIUM OLEANDER	A, H	The concentration of equivalent dry Nerium oleander in the product must be no more than 1mg/Kg or 1mg/L or 0.0001%.

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3468	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%.
3469	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%.
3470	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%.
3471	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%.
3472	NERYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3473	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%.
3474	NICKEL	H	Only for use as an active homoeopathic ingredient.
3475	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3476	NICOTINAMIDE	A, E, H	
3477	NICOTINAMIDE ASCORBATE	A, E	
3478	NICOTINAMIDE RIBOSIDE CHLORIDE	A	Ribose is a mandatory component of nicotinamide riboside chloride. Only permitted for use in medicines limited to oral routes of administration. The maximum recommended daily dose of the medicine must not provide more than 300 mg of nicotinamide riboside chloride. The following warning statement (or words to the same effect) is required on the medicine label:

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			- (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’.
3479	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.
3480	NIGELLA DAMASCENA	A, H	
3481	NIGELLA SATIVA	A, E, H	
3482	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3483	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%.
3484	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%.
3485	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%.
3486	NONFAT DRY MILK	E, H	
3487	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%.
3488	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3489	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%.
3490	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%.

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3491	NONOXINOL 9	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
3492	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%.
3493	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%.
3494	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%.
3495	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%.
3496	NOTOPTERYGIUM FORBESII	A, H	
3497	NOTOPTERYGIUM INCISIUM	A, H	
3498	NUPHAR JAPONICA	A, H	
3499	NUPHAR LUTEA	A, H	
3500	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%.
3501	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).
3502	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%.
3503	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%.
3504	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%.
3505	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 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'.
3506	NYLON	E	Only for use in topical medicines for dermal application.
3507	NYLON 6/12	E	Only for use in topical medicines for dermal application.

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3508	NYLON-12	E	Only for use in topical medicines for dermal application.
3509	NYMPHAEA ALBA	A, E, H	
3510	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.
3511	NYMPHAEA ODORATA	A, H	
3512	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%.
3513	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%.
3514	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.

3515	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal.
3516	OATMEAL COLLOIDAL	A, E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal.
3517	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%.
3518	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%.
3519	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%.

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	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%.
3520	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.
3521	OCIMUM MINIMUM	A, H	
3522	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%.
3523	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%.
3524	OCTACOSANOL	E	
3525	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%.
3526	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3527	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%.
3528	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%.
3529	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%.
3530	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%.
3531	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%.
3532	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%.
3533	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%.
3534	OCTOCRYLENE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3535	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3536	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%.
3537	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.
3538	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3539	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%.
3540	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3541	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).
3542	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3543	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).
3544	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.
3545	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%.
3546	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3547	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.
3548	OCTYLDODECYL CITRATE	E	Only for use in topical medicines

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	CROSSPOLYMER		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%.
3549	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
3550	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%.
3551	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%.
3552	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%.
3553	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.
3554	OENANTHE CROCATA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.

3555	OENOTHERA BIENNIS	A, E, H	
3556	OENOTHERA STRICTA	A, H	
3557	OKOUBAKA AUBREVILLEI	A, H	
3558	OLDENLANDIA DIFFUSA	A, E, H	
3559	OLEA EUROPAEA	A, E, H	
3560	OLEIC ACID	E	
3561	OLETH-10	E	Only for use in topical medicines for dermal application.
3562	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%.
3563	OLETH-20	E	Only for use in topical medicines for dermal application.
3564	OLETH-3	E	Only for use in topical medicines for dermal application.
3565	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%.
3566	OLETH-5	E	Only for use in topical medicines for dermal application.
3567	OLEYL ALCOHOL	E	Only for use in topical medicines

			for dermal application.
3568	OLIBANUM OIL	A, E, H	
3569	OLIVE OIL	A, E, H	
3570	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).'
3571	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).
3572	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: - (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.'
3573	ONION	E	
3574	ONION OIL	A, H	
3575	ONONIS SPINOSA	A, E, H	
3576	ONOPORDUM ACANTHIUM	A, H	
3577	ONOSMODIUM VIRGINIANUM	A, H	
3578	OPHIOPOGON JAPONICUS	A, H	
3579	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%.
3580	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%.
3581	OPUNTIA FICUS-INDICA	A, H	
3582	ORANGE	E	
3583	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%.
3584	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.
3585	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%.
3586	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%.
3587	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.
3588	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.
3589	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.
3590	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%.
3591	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.
3592	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%.
3593	ORANGE OIL TERPENELESS	A, E, H	When used internally, oxedrine is a mandatory component of orange oil terpeneless. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3594	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%.
3595	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.
3596	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%.
3597	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.

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3598	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).
3599	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%.
3600	ORIGANUM OIL SPANISH	A, E, H	
3601	ORIGANUM VULGARE	A, E, H	
3602	ORNITHINE	A, E	
3603	ORNITHINE ASPARTATE	A, E	
3604	ORNITHINE MONOHYDROCHLORIDE	A, E	
3605	ORNITHOGALUM UMBELLATUM	A, H	
3606	OROSTACHYS FIMBRIATA	A, H	
3607	OROXYLUM INDICUM	A, H	
3608	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%.
3609	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%.
3610	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%.
3611	ORRIS ROOT OIL	A, E, H	
3612	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%.
3613	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%.
3614	ORTHOSIPHON ARISTATUS	A, H	
3615	ORYZA SATIVA	A, E, H	
3616	ORYZANOL	E	
3617	OSBECKIA CHINENSIS	A, H	
3618	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%.
3619	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%.
3620	OTTELIA ALISMOIDES	A, H	
3621	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%.
3622	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3623	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%.
3624	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%.
3625	OXALIS ACETOSELLA	A, H	
3626	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%.
3627	OXIDISED TAPIOCA STARCH	E	
3628	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

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			this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3629	OYSTER	E	The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
3630	OYSTER SHELL	A, E, H	The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.