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

Note: See sections 5 and 6.

Permissible ingredients and requirements

Column 1	Column 2	Column 3	Column 4
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2860	KADSURA COCCINEA	A, H	
2861	KAEMPFERIA GALANGA	A, H	
2862	KALMIA LATIFOLIA	A, H	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%.
2863	KAOLIN	E	
2864	KELP DRY	A, H	Iodine is a mandatory component of Kelp dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per

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			maximum recommended daily dose.
2865	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.
2866	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%.
2867	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%.
2868	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'.
2869	KIDNEY BEAN	E	
2870	KIRSCH	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2871	KIWI FRUIT	E	
2872	KNAUTIA ARVENSIS	A, H	
2873	KOREAN GINSENG ROOT DRY	A, H	
2874	KOREAN GINSENG ROOT POWDER	A, H	
2875	KRAMERIA IXIENA	A, H	
2876	KRAMERIA LAPPACEA	A, H	
2877	KUNZEA AMBIGUA	A	Only for use when the plant preparation is essential oil. Only for use when the route of administration is topical or inhalation. When the dosage form is essential oil, a restricted flow insert must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only' - (UNDILU) 'Not to be applied undiluted to the skin except on the advice of a health care practitioner'. When the dosage form is other

			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'.
2878	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%.
2879	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%.
2880	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%.
2881	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.
2882	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%.
2883	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%.
2884	L-MENTHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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2885	L-ROSE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2886	LABDANUM ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2887	LABDANUM GUM EXTRACT ETHYL ESTER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance and the total fragrance concentration in a medicine is no more than 1%.
2888	LABDANUM OIL	A, E, H	
2889	LABURNUM ANAGYROIDES	A, H	Sparteine is a mandatory component of Laburnum anagyroides. The concentration of sparteine in the medicine must be no more than 0.001%.
2890	LACTALBUMIN	E	
2891	LACTIC ACID	A, E, H	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in

			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.
2892	LACTITOL	E	
2893	LACTITOL MONOHYDRATE	E	
2894	LACTO-N-NEOTETRAOSE	A	Only to be used in a medicine where Glycom A/S (Client ID 76983), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 20 August 2023. Lactose is a mandatory component of lacto-N-neotetraose. The route of administration for medicines that contain lacto-N-neotetraose must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than: (a) 1.5 g of lacto-N-neotetraose to individuals aged 4 years and older; and (b) 0.6 g of lacto-N-neotetraose to individuals aged up to 3 years (inclusive).
2895	LACTOBACILLUS ACIDOPHILUS	A	
2896	LACTOBACILLUS AMYLOVORUS	A	
2897	LACTOBACILLUS BREVIS	A	
2898	LACTOBACILLUS CASEI	A	

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2899	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2900	LACTOBACILLUS CRISPATUS	A	
2901	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2902	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2903	LACTOBACILLUS FERMENTUM	A	
2904	LACTOBACILLUS GALLINARUM	A	
2905	LACTOBACILLUS GASSERI	A	
2906	LACTOBACILLUS HELVETICUS	A	
2907	LACTOBACILLUS JOHNSONII	A	
2908	LACTOBACILLUS KEFIRANOFACIENS	A	
2909	LACTOBACILLUS KEFIRGRANUM	A	
2910	LACTOBACILLUS KEFIRI	A	
2911	LACTOBACILLUS PARACASEI	A	
2912	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2913	LACTOBACILLUS PLANTARUM	A	
2914	LACTOBACILLUS REUTERI	A	
2915	LACTOBACILLUS RHAMNOSUS	A	
2916	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2917	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2918	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2919	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%.
2920	LACTOSE	E	
2921	LACTOSE MONOHYDRATE	E	

2922	LACTUCA SATIVA	A, H	
2923	LACTUCA VIROSA	A, H	
2924	LACTULOSE	E	
2925	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.
2926	LAGENARIA VULGARIS	A, H	
2927	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.
2928	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.
2929	LAMINARIA JAPONICA	A, E, H	Iodine is a mandatory component of Laminaria japonica. Only for external use when the

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			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.
2930	LAMIUM ALBUM	A, H	
2931	LANETH-5	E	Only for use in topical medicines for dermal application.
2932	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2933	LANOLIN OIL	E	Only for use in topical medicines for dermal application.
2934	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2935	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.
2936	LARIX ARABINOGALACTAN	A, E	The concentration of polysaccharides in the ingredient must be greater than or equal to 85%. The ingredient must be derived from Larix occidentalis or Larix larcinia. Only for use in oral medicines or topical medicines for dermal application, and not to be included in topical products intended for use in the eye. The maximum recommended daily dose of Larix

			arabinogalactan in oral medicines must not be more than 15 grams. The concentration of Larix arabinogalactan in topical medicines for dermal application must not exceed 5.0%.
2937	LARIX DECIDUA	A, H	
2938	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.
2939	LARREA TRIDENTATA	A, H	The medicine requires the following warning statement on the medicine label: - (CHAP) 'WARNING: Chaparral may harm the liver in some people - use only under supervision of a health care professional'.
2940	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.
2941	LAURAMINE OXIDE	E	
2942	LAUREL LEAF OIL	A, H	
2943	LAURETH-10	E	Only for use in topical medicines for dermal application.
2944	LAURETH-12	E	Only for use in topical medicines for dermal application.
2945	LAURETH-2	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.4%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
2946	LAURETH-23	E	Only for use in topical medicines for dermal application.
2947	LAURETH-3	E	Only for use in topical medicines for dermal application.
2948	LAURETH-4	E	Only for use in topical medicines for dermal application.
2949	LAURETH-7	E	Only for use in topical medicines for dermal application.
2950	LAURETH-8	E	
2951	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.
2952	LAURIL MACROGOL 400 DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
2953	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.

2954	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%.
2955	LAURUS NOBILIS	A, E, H	When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is less than or equal to 15 millilitres, a restricted flow insert must be fitted on the container. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is greater than 15 millilitres, a child resistant closure must be fitted on the container. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25%, the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
2956	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

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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%.
2957	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2958	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%.
2959	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.
2960	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%.
2961	LAURYL PEG-10 TRIS(TRIMETHYLSILOXY)SILYL	E	Only for use in topical medicines for dermal

	ETHYL DIMETICONE		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%.
2962	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%.
2963	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.
2964	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.
2965	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2966	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.

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2967	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%.
2968	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2969	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%.
2970	LAVANDIN OIL ABRIAL	A, E, H	
2971	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%.
2972	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%.

2973	LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia subsp. angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.
2974	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%.
2975	LAVENDER OIL	A, E, H	
2976	LAWSONIA INERMIS	A, H	
2977	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2978	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.
2979	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%.
2980	LECITHIN	A, E	
2981	LEDEBOURIELLA SESELOIDES	A, H	
2982	LEDUM PALUSTRE	A, H	Beta-arbutin is a mandatory component of Ledum palustre.

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			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.
2983	LEMNA MINOR	A, H	
2984	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.
2985	LEMON BALM LEAF DRY	A, H	
2986	LEMON BALM LEAF POWDER	A, E, H	
2987	LEMON OIL	A, E, H	When used internally, oxedrine is a mandatory component of lemon oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must

			be included on the medicine label unless the medicine is: a) steam distilled or rectified; or b) for internal use; or c) contains 0.05% or less of lemon oil; or d) for use in soaps or bath or shower gels that are washed off the skin.
2988	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.
2989	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.
2990	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%.
2991	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.

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2992	LEMONGRASS OIL	A, E, H	
2993	LENS CULINARIS	A, H	
2994	LENTIL	E	
2995	LENTINULA EDODES	A, E, H	
2996	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%.
2997	LEONURUS CARDIACA	A, E, H	
2998	LEONURUS SIBIRICUS	A, E, H	
2999	LEPIDIUM APETALUM	A, H	
3000	LEPIDIUM MEYENII	A	Only for use in oral medicines when the plant part is tuber and the plant preparation is dry. The maximum recommended daily dose must be no more than 3.5g of Lepidium meyenii dried tuber (or its extract equivalent).
3001	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.
3002	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’
3003	LESPEDEZA CAPITATA	A, H	
3004	LETTUCE	E	
3005	LEUCINE	A, E	
3006	LEUZEA UNIFLORUM	A, H	
3007	LEVISTICUM OFFICINALE	A, H	
3008	LEVOCARNITINE	A	
3009	LEVOCARNITINE FUMARATE	A	
3010	LEVOCARNITINE HYDROCHLORIDE	A	
3011	LEVOCARNITINE MAGNESIUM CITRATE	A	
3012	LEVOCARNITINE TARTRATE	A	
3013	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,

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			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.
3014	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.
3015	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
3016	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%.
3017	LIGHT KAOLIN	E	
3018	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.
3019	LIGHT MAGNESIUM OXIDE	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of light magnesium oxide. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.

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3020	LIGUSTICUM SINENSE	A, H	
3021	LIGUSTICUM STRIATUM	A, E, H	
3022	LIGUSTRUM LUCIDUM	A, H	
3023	LILIUM BROWNII	A, H	
3024	LILIUM CANDIDUM	A, E, H	
3025	LILIUM LANCIFOLIUM	A, H	
3026	LILIUM LONGIFLORUM	A, H	
3027	LIME FRUIT	E	
3028	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%.
3029	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.
3030	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.
3031	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%.
3032	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%.
3033	LIME TREE FLOWER DRY	A, H	
3034	LIME TREE FLOWER POWDER	A, H	
3035	LIME, ESSENCE	E	
3036	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%.
3037	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.
3038	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

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			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	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%.
3040	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%.
3041	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%.
3042	LINALYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3043	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%.
3044	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%.
3045	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%.
3046	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%.

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3047	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%.
3048	LINDERA STRYCHNIFOLIA	A, H	
3049	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%.
3050	LINOLEIC ACID	E	
3051	LINOLENIC ACID	E	
3052	LINSEED DRY	A, E, H	
3053	LINSEED OIL	A, E, H	
3054	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.
3055	LINSEED POWDER	A, E, H	
3056	LINUM USITATISSIMUM	A, E, H	
3057	LIPASE	A	Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline.
3058	LIPPIA DULCIS	A, H	

3059	LIQUID GLUCOSE	E	
3060	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.
3061	LIQUIDAMBAR FORMOSANA	A, H	
3062	LIQUIDAMBAR ORIENTALIS	A, H	
3063	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3064	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%.
3065	LIQUIDAMBAR TAIWANIANA	A, H	
3066	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%.
3067	LIQUORICE DRY	A, E, H	
3068	LIQUORICE LIQUID EXTRACT	A, E, H	
3069	LIQUORICE POWDER	A, E, H	
3070	LITCHI CHINENSIS	A, H	
3071	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
3072	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.

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3073	LITSEA CUBEBA	A, E, H	
3074	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%.
3075	LOBARIA PULMONARIA	A, H	
3076	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.
3077	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.
3078	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.
3079	LOLIUM PERENNE	A, H	
3080	LOLIUM TEMULENTUM	A, H	
3081	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%.
3082	LONICERA CAPRIFOLIUM	A, E, H	
3083	LONICERA JAPONICA	A, E, H	

3084	LONICERA PERICLYMENUM	A, H	
3085	LOPHATHERUM GRACILE	A, H	
3086	LOQUAT	E	
3087	LORANTHUS PARASITICUS	A, H	
3088	LOROPETALUM CHINENSIS	A, H	
3089	LOTUS CORNICULATUS	A, H	
3090	LOVAGE OIL	A, E, H	
3091	LOVAGE ROOT DRY	A, H	
3092	LOVAGE ROOT POWDER	A, H	
3093	LUDWIGIA PROSTRATA	A, H	
3094	LUFFA CYLINDRICA	A, H	
3095	LUFFA PURGANS	A, H	
3096	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.
3097	LYCHEE	E	
3098	LYCIUM BARBARUM	A, H	
3099	LYCIUM CHINENSE	A, E, H	
3100	LYCOPENE	A, E	
3101	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.
3102	LYCOPODIUM ANNOTINUM	A, H	
3103	LYCOPODIUM CLAVATUM	A, H	
3104	LYCOPODIUM COMPLANATUM	A, H	
3105	LYCOPUS EUROPAEUS	A, H	
3106	LYCOPUS LUCIDUS	A, H	
3107	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%.

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3108	LYGODIUM JAPONICUM	A, H	
3109	LYSIMACHIA CHRISTINAE	A, H	
3110	LYSIMACHIA VULGARIS	A, H	
3111	LYSINE	A, E	
3112	LYSINE HYDROCHLORIDE	A, E	
3113	LYTHRUM HYSSOPIFOLIA	A, H	
3114	LYTHRUM SALICARIA	A, H	
3115	LYTHRUM VERTICILLATUM	A, H	
3116	MACADAMIA INTEGRIFOLIA	A, E	
3117	MACADAMIA NUT	E	
3118	MACADAMIA NUT OIL	E	
3119	MACADAMIA TERNIFOLIA	A, E, H	
3120	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%.
3121	MACE OIL	A, H	Safrole is a mandatory component of Mace oil. When used internally, the concentration of safrole in the medicine must be no more than 0.1%. When used topically, the concentration of safrole in the medicine must be no more than 1.0%. When the concentration of mace oil in the preparation is more than 50% and the nominal capacity of the container is 25 mL or less, a restricted flow insert must be fitted on the container.
3122	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.
3123	MACROGOL 1000	E	
3124	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3125	MACROGOL 1500	E	
3126	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%.
3127	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3128	MACROGOL 20000	E	
3129	MACROGOL 300	E	
3130	MACROGOL 3000	E	
3131	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.
3132	MACROGOL 40	E	Only for use in topical

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			medicines for dermal application.
3133	MACROGOL 400	E	
3134	MACROGOL 4000	E	
3135	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3136	MACROGOL 600	E	
3137	MACROGOL 6000	E	
3138	MACROGOL 600000	E	
3139	MACROGOL 800	E	
3140	MACROGOL 8000	E	
3141	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%.
3142	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3143	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3144	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.
3145	MAGNESIUM ASCORBATE	A, E, H	
3146	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	
3147	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3148	MAGNESIUM ASPARTATE	A, E, H	

3149	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3150	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3151	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3152	MAGNESIUM CHLORIDE 4.5-HYDRATE	A	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium chloride 4.5-hydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) 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 CHLORIDE HEXAHYDRATE	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium chloride hexahydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) 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 CITRATE	A, E, H	
3155	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	
3156	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	
3157	MAGNESIUM DIGLUTAMATE	A, E, H	
3158	MAGNESIUM GLUCONATE	A, E, H	
3159	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3160	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.
3161	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.
3162	MAGNESIUM HYDROGEN PHOSPHATE	H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium hydrogen phosphate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive)

			provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3163	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. The requirements specified in paragraph (a) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2021; - released for supply before or on 1 March 2022; and - the following warning statement is not specified on the label: - (LAX6) 'Contains magnesium, which may have a

		laxative effect or cause diarrhoea' (or words to that effect). (a) When the medicine is not promoted or marketed as laxative, contains more than 2 g magnesium hydroxide per maximum recommended daily dose, the following warning statements are required on the label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect'. The requirements specified in paragraphs (b) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (b) Magnesium is a mandatory component of magnesium hydroxide. (c) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (d) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3164	MAGNESIUM LYSINATE	A	Only for use in oral medicines.
3165	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3166	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3167	MAGNESIUM OROTATE	A, E, H	
3168	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3169	MAGNESIUM OXIDE	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium oxide. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total

			magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3170	MAGNESIUM PHOSPHATE PENTAHYDRATE	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium phosphate pentahydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;

			(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3171	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. The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1

			and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (b) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3172	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.
3173	MAGNESIUM STEARATE	E	
3174	MAGNESIUM SULFATE DIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5g. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium sulfate dihydrate.

			(b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3175	MAGNESIUM SULFATE HEPTAHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5 g. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory

			component of magnesium sulfate heptahydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3176	MAGNESIUM SULFATE MONOHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5 g. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1

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			March 2022. (a) Magnesium is a mandatory component of magnesium sulfate monohydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3177	MAGNESIUM SULFATE TRIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5 g. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or

			after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium sulfate trihydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3178	MAGNESIUM TRISILICATE	E	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1

			March 2022. (a) Magnesium is a mandatory component of magnesium trisilicate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) 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). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3179	MAGNOLIA GLAUCA	A, H	
3180	MAGNOLIA LILIFLORA	A, H	
3181	MAGNOLIA OBOVATA	A, H	
3182	MAGNOLIA OFFICINALIS	A, E, H	
3183	MAGNOLIA SALICIFOLIA	A, H	
3184	MAIZE	E	
3185	MAIZE BRAN	E	

3186	MAIZE OIL	A, E, H	
3187	MAIZE STARCH	A, E, H	
3188	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3189	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.
3190	MALPIGHIA GLABRA	A, E, H	
3191	MALT EXTRACT	E	
3192	MALTITOL	E	
3193	MALTITOL SOLUTION	E	
3194	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.
3195	MALTOL	E	
3196	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%.
3197	MALTOSE	E	
3198	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
3199	MALUS SYLVESTRIS	A, H	
3200	MALVA MOSCHATA	A, H	
3201	MALVA SYLVESTRIS	A, E, H	
3202	MALVA VERTICILLATA	A, H	
3203	MANDARIN	E	
3204	MANDARIN OIL	E	Permitted for use only in

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			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%.
3205	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.
3206	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%.
3207	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%.
3208	MANDARINAL 32048	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

3209	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%.
3210	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3211	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3212	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3213	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3214	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.
3215	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3216	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.

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3217	MANGANESE GLUCONATE	A, E, H	
3218	MANGANESE GLYCEROPHOSPHATE	A, E, H	
3219	MANGANESE OXIDE	A, E, H	
3220	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3221	MANGANESE SULFATE TETRAHYDRATE	A, E, H	
3222	MANGIFERA INDICA	A, E, H	
3223	MANGO	E, H	
3224	MANIHOT ESCULENTA	A, H	
3225	MANNITOL	E	
3226	MARANTA ARUNDINACEA	A, H	
3227	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3228	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).
3229	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).
3230	MARRUBIUM VULGARE	A, E, H	
3231	MARSDENIA CUNDURANGO	A, H	
3232	MARSHMALLOW ROOT DRY	A, H	

3233	MARSHMALLOW ROOT POWDER	A, H	
3234	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%.
3235	MASTIC	A, H	
3236	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%.
3237	MATRICARIA CHAMOMILLA	A, E, H	
3238	MATRICARIA FLOWER DRY	A, E, H	
3239	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'.
3240	MECOBALAMIN (CO-METHYLCOBALAMIN)	A	Only for use in oral medicines.
3241	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.
3242	MEDIUM CHAIN TRIGLYCERIDES	E	
3243	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

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			must also have a child resistant closure.
3244	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.
3245	MELALEUCA CITRINA	A, H	
3246	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.
3247	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

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			nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3248	MELALEUCA 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.
3249	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.
3250	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

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			to 25 millilitres the medicine must also have a child resistant closure.
3251	MELICOPE PTELEIFOLIA	A, H	
3252	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%.
3253	MELISSA OFFICINALIS	A, E, H	
3254	MELON	E	
3255	MENADIONE SODIUM BISULFITE	E	
3256	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.
3257	MENISPERMUM CANADENSE	A, H	
3258	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.
3259	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

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			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.
3260	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.
3261	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.

3262	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.

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3263	MENTHA PULEGIUM	A, H	D-pulegone, menthol and volatile oil components (of Mentha pulegium) are mandatory components of Mentha pulegium. When the nominal capacity of the container is more than 15 millilitres, the concentration of d-pulegone in the medicine must be no more than 4%. When the concentration of d-pulegone in the preparation is more than 4% and the nominal capacity of the container is 15 millilitres or less, the medicine must have a child resistant closure and restricted flow insert fitted on the container. The medicine requires the following warning statements on the medicine label: - (NTAKEN) 'Not to be taken'; - (CHILD) 'Keep out of reach of children' (or words to that effect). When the medicine is for topical use for dermal application: a) the maximum recommended daily dose must not contain more than 150 mg of Mentha pulegium oil or distillate; b) the medicine must not be intended for use in the eye or on damaged skin; c) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; d) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). e) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the

			following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. f) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use: a) the maximum recommended daily dose must not contain more than 50 mg of Mentha pulegium oil or distillate; b) the maximum recommended daily dose must not contain more than 1 gram of menthol.
3264	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.
3265	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.
3266	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

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			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.
3267	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.
3268	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%.

3269	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%.
3270	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.

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			When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3271	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%.
3272	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%.
3273	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%.
3274	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3275	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%.
3276	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%.
3277	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).
3278	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%.
3279	MENTHYL LACTATE	E	
3280	MENYANTHES TRIFOLIATA	A, H	
3281	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient.
3282	MERCURY	H	Only for use as an active

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			homoeopathic ingredient.
3283	METACRESOL	E	Only for use in topical medicines for dermal application.
3284	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3285	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%.
3286	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%.
3287	METHIONINE	A, E	
3288	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%.
3289	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%.

3290	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%.
3291	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%.
3292	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%.
3293	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%.
3294	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3295	METHYL ANISATE	E	Permitted for use only in combination with other permitted ingredients as a

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			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3296	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%.
3297	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3298	METHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3299	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%.
3300	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%.
3301	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%.
3302	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%.
3303	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%.
3304	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3305	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%.
3306	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%.
3307	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%.
3308	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%.
3309	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%.
3310	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%.
3311	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3312	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%.
3313	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%.
3314	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%.
3315	METHYL GLUCETH-10	E	Only for use in topical

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			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.
3316	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.
3317	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%.
3318	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3319	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3320	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3321	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3322	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%.
3323	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%.
3324	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%.
3325	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%.
3326	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%.

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3327	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3328	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3329	METHYL HYDROXYBENZOATE	E	
3330	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%.
3331	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%.
3332	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%.
3333	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%.
3334	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%.
3335	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%.
3336	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%.
3337	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%.
3338	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%.

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3339	METHYL METHACRYLATE	E	
3340	METHYL METHACRYLATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When the concentration of methyl methacrylate crosspolymer is greater than 1%, the medicine must not be intended for use on damaged skin. The concentration in the medicine must not be more than 4.85%.
3341	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%.
3342	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%.
3343	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%.
3344	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%.
3345	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%.
3346	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%.
3347	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%.
3348	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

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			medicine must be no more than 5%.
3349	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%.
3350	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%.
3351	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%.
3352	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%.
3353	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%.
3354	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

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			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'.
3355	METHYL STEARATE	E	
3356	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%.
3357	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%.
3358	METHYL-3-	E	Permitted for use only in

	METHYLTHIOPROPIONATE		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%.
3359	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%.
3360	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%.
3361	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%.
3362	METHYLCELLULOSE	A, E	
3363	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%.
3364	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%.
3365	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).
3366	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%.
3367	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%.
3368	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%.
3369	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%.
3370	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3371	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%.
3372	MICROCALICIUM ARENARIUM	A, H	
3373	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%.
3374	MICROCOS PANICULATA	A, H	
3375	MICROCRYSTALLINE CELLULOSE	E	
3376	MICROCRYSTALLINE WAX	E	Only for use as an excipient in

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			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'.
3377	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%.
3378	MILK THISTLE FRUIT DRY	A, H	
3379	MILK THISTLE FRUIT POWDER	A, H	
3380	MILLET	E	
3381	MILLETTIA DIELSIANA	A, H	
3382	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%.
3383	MIMULUS GUTTATUS	A, H	
3384	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.
3385	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%.
3386	MITCHELLA REPENS	A, H	
3387	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3388	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	

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3389	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%.
3390	MODIFIED FOOD STARCH	E	
3391	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%.
3392	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.
3393	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.

3394	MOMORDICA BALSAMINA	A, H	
3395	MOMORDICA CHARANTIA	A, H	
3396	MOMORDICA COCHINCHINENSIS	A, H	
3397	MONARDA DIDYMA	A, H	
3398	MONO- AND DI- GLYCERIDES	E	
3399	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3400	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3401	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.
3402	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.
3403	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.
3404	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than

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			5%.
3405	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.
3406	MONOPHOSPHOTHIAMINE	A	
3407	MONOPHOSPHOTHIAMINE DIHYDRATE	A	
3408	MONOPOTASSIUM GLUTAMATE	A, E	
3409	MONOSODIUM DIHYDROGEN CITRATE	E	
3410	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	
3411	MONSTERA DELICIOSA	A, H	
3412	MONTAN WAX	E	
3413	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%..
3414	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).
3415	MORINDA OFFICINALIS	A, H	
3416	MORINGA OLEIFERA	A, H	
3417	MORUS ALBA	A, H	
3418	MORUS BOMBYCIS	A, H	
3419	MORUS NIGRA	A, E, H	

3420	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%.
3421	MOTHERWORT HERB DRY	A, H	
3422	MOTHERWORT HERB POWDER	A, H	
3423	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%.
3424	MULBERRY	E	
3425	MUNG BEAN	E	
3426	MURRAYA KOENIGII	A, H	
3427	MURRAYA PANICULATA	A, H	
3428	MUSA X PARADISIACA	A, H	
3429	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3430	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%.
3431	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3432	MUSKS	H	Only for use as an active homoeopathic ingredient.
3433	MUSTARD	E	Allyl isothiocyanate is a

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			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%.
3434	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%.
3435	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%.
3436	MYOSOTIS ARVENSIS	A, H	
3437	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%.
3438	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%.
3439	MYRICA CERIFERA	A, E, H	
3440	MYRISTIC ACID	E	
3441	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%.
3442	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).
3443	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.

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3444	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3445	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3446	MYROXYLON BALSAMUM	A, E, H	
3447	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3448	MYRRH	A, H	
3449	MYRRH OIL	A, E, H	
3450	MYRRH RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3451	MYRRHIS ODORATA	A, H	
3452	MYRSINE AFRICANA	A, H	
3453	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%.
3454	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%.
3455	MYRTLE ESSENCE MAX	E	Permitted for use only in

			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3456	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%.
3457	MYRTUS COMMUNIS	A, E, H	
3458	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.
3459	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%.
3460	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

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			medicine must be no more than 5%.
3461	N-HEXYL 2-BUTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3462	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%.
3463	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3464	NARDOSTACHYS CHINENSIS	A, H	
3465	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%.
3466	NASTURTIUM OFFICINALE	A, E, H	
3467	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.
3468	NAUCLEA OFFICINALIS	A, H	
3469	NELUMBO NUCIFERA	A, H	
3470	NELUMBO NUCIFERA FLOWER WAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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			for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
3471	NEOHESPERIDIN-DIHYDROCHALCONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%
3472	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%.
3473	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%.
3474	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%.
3475	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.
3476	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3477	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3478	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%.
3479	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%.
3480	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%.
3481	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

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			fragrance concentration in a medicine must be no more 1%.
3482	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%.
3483	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%.
3484	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%.
3485	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%.
3486	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%.
3487	NICKEL	H	Only for use as an active homoeopathic ingredient.
3488	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3489	NICOTINAMIDE	A, E, H	
3490	NICOTINAMIDE ASCORBATE	A, E	
3491	NICOTINAMIDE RIBOSIDE CHLORIDE	A	Only to be used in a medicine where Chromadex Inc (Client ID 68566), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 02 December 2021. 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.

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			The following warning statement (or words to the same effect) is required on the medicine label: - (NTAKEN12) 'Not to be taken by children under 12 years old.' When the maximum recommended daily dose of the medicine provides greater than 230 mg of nicotinamide riboside chloride, the following warning statement is required on the medicine label: - (PREG) 'Not recommended for use during pregnancy or lactation'.
3492	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.
3493	NIGELLA DAMASCENA	A, H	
3494	NIGELLA SATIVA	A, E, H	
3495	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3496	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%.
3497	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%.
3498	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%.
3499	NONFAT DRY MILK	E, H	
3500	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%.
3501	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3502	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%.
3503	NONOXINOL 5	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3504	NONOXINOL 9	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
3505	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%.
3506	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%.
3507	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%.
3508	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%.

3509	NOTOPTERYGIUM FORBESII	A, H	
3510	NOTOPTERYGIUM INCISIUM	A, H	
3511	NUPHAR JAPONICA	A, H	
3512	NUPHAR LUTEA	A, H	
3513	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%.
3514	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).
3515	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

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			concentration of safrole in the medicine must be no more than 1%.
3516	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%.
3517	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%.
3518	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'.
3519	NYLON	E	Only for use in topical medicines for dermal

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			application.
3520	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3521	NYLON-12	E	Only for use in topical medicines for dermal application.
3522	NYMPHAEA ALBA	A, E, H	
3523	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.
3524	NYMPHAEA ODORATA	A, H	
3525	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%.
3526	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%.

3527	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.
3528	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal.
3529	OATMEAL COLLOIDAL	A, E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal.
3530	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%.
3531	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%.
3532	OCIMUM BASILICUM	A, E, H	When the plant preparation is oil or distillate, Methyl chavicol, eugenol, methyleugenol and cineole are

		mandatory components of Ocimum basilicum. The concentration of methyleugenol in the medicine must not exceed 1%. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25 millilitres or less, a restricted flow insert must be fitted on the container, and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect). When the concentration of cineole OR eugenol in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres and the following warning statements must be included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cineole OR eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of cineole OR eugenol in the preparation is more than 25% and the nominal capacity of the

			container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container. When the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of eugenol and the concentration of eugenol in the product must not be greater than 25%.
3533	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

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			closure fitted on the container.
3534	OCIMUM MINIMUM	A, H	
3535	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%.
3536	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%.
3537	OCTACOSANOL	E	
3538	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%.
3539	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3540	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%.
3541	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%.
3542	OCTAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			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%.
3543	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%.
3544	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%.
3545	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%.
3546	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%.
3547	OCTHILINONE	E	Only for use in topical medicines for dermal application.
3548	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).
3549	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3550	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

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			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3551	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.
3552	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3553	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%.
3554	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3555	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).
3556	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3557	OCTYL SALICYLATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 5%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3558	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.
3559	OCTYLBICYCLOHEPTENEDICARBOXIMIDE	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (OBCARB) 'Contains octylbicycloheptenedicarboximide' (or words to that effect).
3560	OCTYLDODECANOL	E	Only for use in topical

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			medicines for dermal application.
3561	OCTYLDODECETH-25	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
3562	OCTYLDODECYL CITRATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 12%.
3563	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
3564	OCTYLDODECYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3565	OCTYLDODECYL XYLOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1.5%.

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

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			mg/L or 0.0001%.
3577	OLETH-20	E	Only for use in topical medicines for dermal application.
3578	OLETH-3	E	Only for use in topical medicines for dermal application.
3579	OLETH-3 PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.12%.
3580	OLETH-5	E	Only for use in topical medicines for dermal application.
3581	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3582	OLIBANUM OIL	A, E, H	
3583	OLIVE	E	
3584	OLIVE OIL	A, E, H	
3585	OMEGA-3 FISH OIL PHYTOSTEROL ESTERS	A	The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'
3586	OMEGA-3-ACID ETHYL ESTERS 60	A	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).
3587	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.'
3588	ONION	E	
3589	ONION OIL	A, H	
3590	ONONIS SPINOSA	A, E, H	
3591	ONOPORDUM ACANTHIUM	A, H	
3592	ONOSMODIUM VIRGINIANUM	A, H	
3593	OPHIOPOGON JAPONICUS	A, H	
3594	OPOPANAX CHIRONIUM	A, E, H	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%.
3595	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%.
3596	OPUNTIA FICUS-INDICA	A, H	
3597	ORANGE	E	
3598	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%.
3599	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.
3600	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%.
3601	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%.
3602	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.
3603	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.
3604	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.
3605	ORANGE OIL COLD PRESSED	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3606	ORANGE OIL DISTILLED	A, E, H	When used internally, oxedrine is a mandatory component of orange oil distilled. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3607	ORANGE OIL SWEET	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3608	ORANGE OIL TERPENELESS	A, E, H	When used internally, oxedrine is a mandatory component of orange oil terpeneless. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3609	ORANGE PEEL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3610	ORANGE PEEL DRIED BITTER	A, E, H	When used internally, oxedrine is a mandatory component of orange peel dried bitter.

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			The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3611	ORANGE PEEL OIL SWEET TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3612	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3613	ORIGANUM MAJORANA	A, H	Beta-arbutin is a mandatory component of Origanum majorana. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. 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).
3614	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%.
3615	ORIGANUM OIL SPANISH	A, E, H	
3616	ORIGANUM VULGARE	A, E, H	
3617	ORNITHINE	A, E	
3618	ORNITHINE ASPARTATE	A, E	
3619	ORNITHINE MONOHYDROCHLORIDE	A, E	
3620	ORNITHOGALUM UMBELLATUM	A, H	
3621	OROSTACHYS FIMBRIATA	A, H	
3622	OROXYLUM INDICUM	A, H	
3623	ORRIS	E	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%.
3624	ORRIS CONCRETE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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			flavour concentration in a medicine must be no more than 5%.
3625	ORRIS ROOT EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3626	ORRIS ROOT OIL	A, E, H	
3627	ORRIS ROOT RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3628	ORTHO-TERT-BUTYLCYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3629	ORTHOSIPHON ARISTATUS	A, H	
3630	ORYZA SATIVA	A, E, H	
3631	ORYZANOL	E	
3632	OSBECKIA CHINENSIS	A, H	
3633	OSMANTHUS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

3634	OSMANTHUS FRAGRANS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3635	OTTELIA ALISMOIDES	A, H	
3636	OXACYCLOHEPTADEC-11-EN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3637	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3638	OXACYCLOHEXADECEN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3639	OXALIC ACID	H	Only for use as an active homoeopathic ingredient.
3640	OXALIS ACETOSELLA	A, H	
3641	OXIDISED MAIZE STARCH	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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3642	OXIDISED TAPIOCA STARCH	E	
3643	OXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3644	OYSTER	E	
3645	OYSTER SHELL	A, E, H	