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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**
2858	KADSURA COCCINEA	A, H	
2859	KAEMPFERIA GALANGA	A, H	
2860	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%.
2861	KAOLIN	E	
2862	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

			maximum recommended daily dose.
2863	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.
2864	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%.
2865	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%.
2866	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';

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			- (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'.
2867	KIDNEY BEAN	E	
2868	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%.
2869	KIWI FRUIT	E	
2870	KNAUTIA ARVENSIS	A, H	
2871	KOREAN GINSENG ROOT DRY	A, H	
2872	KOREAN GINSENG ROOT POWDER	A, H	
2873	KRAMERIA IXIENA	A, H	
2874	KRAMERIA LAPPACEA	A, H	
2875	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'.
2876	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%.
2877	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%.
2878	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%.
2879	L-LIMONENE	E	L-limonene must only be

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			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.
2880	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%.
2881	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%.
2882	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%.
2883	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%.
2884	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%.
2885	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%.
2886	LABDANUM OIL	A, E, H	
2887	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%.
2888	LACTALBUMIN	E	
2889	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.
2890	LACTITOL	E	
2891	LACTITOL MONOHYDRATE	E	
2892	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). The requirements specified in paragraph (a) below apply to a medicine that contains the ingredient that is released for supply after 20 August 2023: (a) One of the following

			statements is required on the medicine label: (i) When the medicine is only for use in individuals aged 2 years and above: 'Not to be taken on the same day with other products containing lacto-N-neotetraose' (or words to that effect); or (ii) When the medicine is for use in children aged less than 2 years: 'Not to be taken on the same day with breastmilk or other products containing lacto-N-neotetraose' (or words to that effect).
2893	LACTO-N-TETRAOSE	A	Only to be used in a medicine where Glycom A/S (Client ID 76983), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 24 January 2024. Lactose is a mandatory component of lacto-N-tetraose. The route of administration for medicines that contain lacto-N-tetraose must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 2 g of lacto-N-tetraose. Not permitted for use in children aged below 1 year. One of the following statements is required on the medicine label: a) When the medicine is only for use in individuals aged above 2 years: 'Not to be taken on the same day with other products containing lacto-N-

			tetraose' (or words to that effect); or b) When the medicine is for use in children aged less than 2 years: 'Not to be taken on the same day with breastmilk or other products containing lacto-N-tetraose' (or words to that effect).
2894	LACTOBACILLUS ACIDOPHILUS	A	
2895	LACTOBACILLUS AMYLOVORUS	A	
2896	LACTOBACILLUS BREVIS	A	
2897	LACTOBACILLUS CASEI	A	
2898	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2899	LACTOBACILLUS CRISPATUS	A	
2900	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2901	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2902	LACTOBACILLUS FERMENTUM	A	
2903	LACTOBACILLUS GALLINARUM	A	
2904	LACTOBACILLUS GASSERI	A	
2905	LACTOBACILLUS HELVETICUS	A	
2906	LACTOBACILLUS JOHNSONII	A	
2907	LACTOBACILLUS KEFIRANOFACIENS	A	
2908	LACTOBACILLUS KEFIRGRANUM	A	
2909	LACTOBACILLUS KEFIRI	A	
2910	LACTOBACILLUS PARACASEI	A	
2911	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2912	LACTOBACILLUS PLANTARUM	A	
2913	LACTOBACILLUS REUTERI	A	
2914	LACTOBACILLUS RHAMNOSUS	A	
2915	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2916	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	

2917	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2918	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%.
2919	LACTOSE	E	
2920	LACTOSE MONOHYDRATE	E	
2921	LACTUCA SATIVA	A, H	
2922	LACTUCA VIROSA	A, H	
2923	LACTULOSE	E	
2924	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.
2925	LAGENARIA VULGARIS	A, H	
2926	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.
2927	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.
2928	LAMINARIA JAPONICA	A, E, H	Iodine is a mandatory component of Laminaria japonica. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2929	LAMIUM ALBUM	A, H	
2930	LANETH-5	E	Only for use in topical medicines for dermal application.
2931	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2932	LANOLIN OIL	E	Only for use in topical medicines for dermal application.
2933	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2934	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material

			of Lantana camara.
2935	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%.
2936	LARIX DECIDUA	A, H	
2937	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.
2938	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'.
2939	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

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			lathyrogenic amino acids.
2940	LAURAMINE OXIDE	E	
2941	LAUREL LEAF OIL	A, H	
2942	LAURETH-10	E	Only for use in topical medicines for dermal application.
2943	LAURETH-12	E	Only for use in topical medicines for dermal application.
2944	LAURETH-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.4%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
2945	LAURETH-23	E	Only for use in topical medicines for dermal application.
2946	LAURETH-3	E	Only for use in topical medicines for dermal application.
2947	LAURETH-4	E	Only for use in topical medicines for dermal application.
2948	LAURETH-7	E	Only for use in topical medicines for dermal application.
2949	LAURETH-8	E	
2950	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.
2951	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%.
2952	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2953	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%.
2954	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

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			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'.
2955	LAURYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2956	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2957	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%.
2958	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.
2959	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%.
2960	LAURYL PEG-10 TRIS(TRIMETHYLSILOXY)SILYL ETHYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
2961	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%.
2962	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.
2963	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.
2964	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2965	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2966	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%.
2967	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2968	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%.
2969	LAVANDIN OIL ABRIAL	A, E, H	
2970	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%.
2971	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%.
2972	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%.
2973	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%.
2974	LAVENDER OIL	A, E, H	
2975	LAWSONIA INERMIS	A, H	
2976	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2977	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.

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2978	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%.
2979	LECITHIN	A, E	
2980	LEDEBOURIELLA SESELOIDES	A, H	
2981	LEDUM PALUSTRE	A, H	Beta-arbutin is a mandatory component of Ledum palustre. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for topical use other than dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. When the route of administration is other than topical, the maximum recommended daily dose must not contain more than 0.001 mg of the equivalent dry herbal material of Ledum palustre.
2982	LEMNA MINOR	A, H	
2983	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.

2984	LEMON BALM LEAF DRY	A, H	
2985	LEMON BALM LEAF POWDER	A, E, H	
2986	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.
2987	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.
2988	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.
2989	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

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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%.
2990	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.
2991	LEMONGRASS OIL	A, E, H	
2992	LENS CULINARIS	A, H	
2993	LENTIL	E	
2994	LENTINULA EDODES	A, E, H	
2995	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%.
2996	LEONURUS CARDIACA	A, E, H	
2997	LEONURUS SIBIRICUS	A, E, H	
2998	LEPIDIUM APETALUM	A, H	
2999	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).
3000	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.

3001	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’
3002	LESPEDEZA CAPITATA	A, H	
3003	LETTUCE	E	
3004	LEUCINE	A, E	
3005	LEUZEA UNIFLORUM	A, H	
3006	LEVISTICUM OFFICINALE	A, H	
3007	LEVOCARNITINE	A	
3008	LEVOCARNITINE FUMARATE	A	
3009	LEVOCARNITINE HYDROCHLORIDE	A	

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3010	LEVOCARNITINE MAGNESIUM CITRATE	A	
3011	LEVOCARNITINE TARTRATE	A	
3012	LEVOMEFOLATE CALCIUM	A	Available for medicines intended for internal use only. Levomefolic acid is a mandatory component of levomefolate calcium. The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate calcium. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.
3013	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.
3014	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
3015	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%.
3016	LIGHT KAOLIN	E	
3017	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.
3018	LIGHT MAGNESIUM OXIDE	A, E, H	Magnesium is a mandatory component of light magnesium oxide. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a

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			laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3019	LIGUSTICUM SINENSE	A, H	
3020	LIGUSTICUM STRIATUM	A, E, H	
3021	LIGUSTRUM LUCIDUM	A, H	
3022	LILIUM BROWNII	A, H	
3023	LILIUM CANDIDUM	A, E, H	
3024	LILIUM LANCIFOLIUM	A, H	
3025	LILIUM LONGIFLORUM	A, H	
3026	LIME FRUIT	E	
3027	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%.
3028	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.
3029	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.
3030	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%.
3031	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%.
3032	LIME TREE FLOWER DRY	A, H	
3033	LIME TREE FLOWER POWDER	A, H	
3034	LIME, ESSENCE	E	
3035	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%.
3036	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.

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3037	LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3038	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%.
3039	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%.
3040	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%.
3041	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%.
3042	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%.
3043	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%.
3044	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%.
3045	LINALYL ISOBUTYRATE	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%.
3046	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%.
3047	LINDERA STRYCHNIFOLIA	A, H	
3048	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%.
3049	LINOLEIC ACID	E	
3050	LINOLENIC ACID	E	
3051	LINSEED DRY	A, E, H	
3052	LINSEED OIL	A, E, H	
3053	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.

3054	LINSEED POWDER	A, E, H	
3055	LINUM USITATISSIMUM	A, E, H	
3056	LIPASE	A	Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline.
3057	LIPPIA DULCIS	A, H	
3058	LIQUID GLUCOSE	E	
3059	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.
3060	LIQUIDAMBAR FORMOSANA	A, H	
3061	LIQUIDAMBAR ORIENTALIS	A, H	
3062	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3063	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%.
3064	LIQUIDAMBAR TAIWANIANA	A, H	
3065	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%.
3066	LIQUORICE DRY	A, E, H	
3067	LIQUORICE LIQUID EXTRACT	A, E, H	
3068	LIQUORICE POWDER	A, E, H	

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3069	LITCHI CHINENSIS	A, H	
3070	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
3071	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
3072	LITSEA CUBEBA	A, E, H	
3073	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%.
3074	LOBARIA PULMONARIA	A, H	
3075	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.
3076	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.
3077	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.
3078	LOLIUM PERENNE	A, H	
3079	LOLIUM TEMULENTUM	A, H	
3080	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%.
3081	LONICERA CAPRIFOLIUM	A, E, H	
3082	LONICERA JAPONICA	A, E, H	
3083	LONICERA PERICLYMENUM	A, H	
3084	LOPHATHERUM GRACILE	A, H	
3085	LOQUAT	E	
3086	LORANTHUS PARASITICUS	A, H	
3087	LOROPETALUM CHINENSIS	A, H	
3088	LOTUS CORNICULATUS	A, H	
3089	LOVAGE OIL	A, E, H	
3090	LOVAGE ROOT DRY	A, H	
3091	LOVAGE ROOT POWDER	A, H	
3092	LUDWIGIA PROSTRATA	A, H	
3093	LUFFA CYLINDRICA	A, H	
3094	LUFFA PURGANS	A, H	
3095	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.
3096	LYCHEE	E	
3097	LYCIUM BARBARUM	A, H	
3098	LYCIUM CHINENSE	A, E, H	
3099	LYCOPENE	A, E	
3100	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.
3101	LYCOPODIUM ANNOTINUM	A, H	
3102	LYCOPODIUM CLAVATUM	A, H	
3103	LYCOPODIUM COMPLANATUM	A, H	

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3104	LYCOPUS EUROPAEUS	A, H	
3105	LYCOPUS LUCIDUS	A, H	
3106	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%.
3107	LYGODIUM JAPONICUM	A, H	
3108	LYSIMACHIA CHRISTINAE	A, H	
3109	LYSIMACHIA VULGARIS	A, H	
3110	LYSINE	A, E	
3111	LYSINE HYDROCHLORIDE	A, E	
3112	LYTHRUM HYSSOPIFOLIA	A, H	
3113	LYTHRUM SALICARIA	A, H	
3114	LYTHRUM VERTICILLATUM	A, H	
3115	MACADAMIA INTEGRIFOLIA	A, E	
3116	MACADAMIA NUT	E	
3117	MACADAMIA NUT OIL	E	
3118	MACADAMIA TERNIFOLIA	A, E, H	
3119	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%.
3120	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.
3121	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.
3122	MACROGOL 1000	E	
3123	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3124	MACROGOL 1500	E	
3125	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%.
3126	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3127	MACROGOL 20000	E	
3128	MACROGOL 300	E	
3129	MACROGOL 3000	E	
3130	MACROGOL 3350	A, E	When used as an active ingredient, can only be supplied as an uncompounded

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			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.
3131	MACROGOL 40	E	Only for use in topical medicines for dermal application.
3132	MACROGOL 400	E	
3133	MACROGOL 4000	E	
3134	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3135	MACROGOL 600	E	
3136	MACROGOL 6000	E	
3137	MACROGOL 600000	E	
3138	MACROGOL 800	E	
3139	MACROGOL 8000	E	
3140	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%.
3141	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3142	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3143	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.

3144	MAGNESIUM ASCORBATE	A, E, H	
3145	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	
3146	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3147	MAGNESIUM ASPARTATE	A, E, H	
3148	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3149	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3150	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3151	MAGNESIUM CHLORIDE 4.5-HYDRATE	A	Magnesium is a mandatory component of magnesium chloride 4.5-hydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).

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			When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3152	MAGNESIUM CHLORIDE HEXAHYDRATE	A, E, H	Magnesium is a mandatory component of magnesium chloride hexahydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3153	MAGNESIUM CITRATE	A, E, H	
3154	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	

3155	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	
3156	MAGNESIUM DIGLUTAMATE	A, E, H	
3157	MAGNESIUM GLUCONATE	A, E, H	
3158	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3159	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.
3160	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.
3161	MAGNESIUM HYDROGEN PHOSPHATE	H	Magnesium is a mandatory component of magnesium hydrogen phosphate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label:

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			- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3162	MAGNESIUM HYDROXIDE	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. Magnesium is a mandatory component of magnesium hydroxide. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label:

			- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3163	MAGNESIUM LYSINATE	A	Only for use in oral medicines.
3164	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3165	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3166	MAGNESIUM OROTATE	A, E, H	
3167	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3168	MAGNESIUM OXIDE	A, E, H	Magnesium is a mandatory component of magnesium oxide. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;

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			the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3169	MAGNESIUM PHOSPHATE PENTAHYDRATE	A, E, H	Magnesium is a mandatory component of magnesium phosphate pentahydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the

			medicine must not be directed for use in infants younger than 12 months of age.
3170	MAGNESIUM PHOSPHATE TRIBASIC	A, E, H	Magnesium is a mandatory component of magnesium phosphate tribasic. The percentage of magnesium from magnesium phosphate tribasic should be calculated based on the molecular weight of magnesium phosphate tribasic. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.

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3171	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.
3172	MAGNESIUM STEARATE	E	
3173	MAGNESIUM SULFATE DIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5g. Magnesium is a mandatory component of magnesium sulfate dihydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.

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

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

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

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			and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3178	MAGNOLIA GLAUCA	A, H	
3179	MAGNOLIA LILIFLORA	A, H	
3180	MAGNOLIA OBOVATA	A, H	
3181	MAGNOLIA OFFICINALIS	A, E, H	
3182	MAGNOLIA SALICIFOLIA	A, H	
3183	MAIZE	E	
3184	MAIZE BRAN	E	
3185	MAIZE OIL	A, E, H	
3186	MAIZE STARCH	A, E, H	
3187	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3188	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.
3189	MALPIGHIA GLABRA	A, E, H	
3190	MALT EXTRACT	E	
3191	MALTITOL	E	
3192	MALTITOL SOLUTION	E	

3193	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.
3194	MALTOL	E	
3195	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%.
3196	MALTOSE	E	
3197	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
3198	MALUS SYLVESTRIS	A, H	
3199	MALVA MOSCHATA	A, H	
3200	MALVA SYLVESTRIS	A, E, H	
3201	MALVA VERTICILLATA	A, H	
3202	MANDARIN	E	
3203	MANDARIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3204	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.

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3205	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%.
3206	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%.
3207	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%.
3208	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%.
3209	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3210	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3211	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3212	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3213	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.
3214	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3215	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.
3216	MANGANESE GLUCONATE	A, E, H	
3217	MANGANESE GLYCEROPHOSPHATE	A, E, H	
3218	MANGANESE OXIDE	A, E, H	
3219	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3220	MANGANESE SULFATE TETRAHYDRATE	A, E, H	
3221	MANGIFERA INDICA	A, E, H	
3222	MANGO	E, H	
3223	MANIHOT ESCULENTA	A, H	
3224	MANNITOL	E	
3225	MARANTA ARUNDINACEA	A, H	
3226	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.

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3227	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).
3228	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).
3229	MARRUBIUM VULGARE	A, E, H	
3230	MARSDENIA CUNDURANGO	A, H	
3231	MARSHMALLOW ROOT DRY	A, H	
3232	MARSHMALLOW ROOT POWDER	A, H	
3233	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%.
3234	MASTIC	A, H	
3235	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%.
3236	MATRICARIA CHAMOMILLA	A, E, H	
3237	MATRICARIA FLOWER DRY	A, E, H	
3238	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'.
3239	MECOBALAMIN (CO-METHYLCOBALAMIN)	A	Only for use in oral medicines.
3240	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.
3241	MEDIUM CHAIN TRIGLYCERIDES	E	

3242	MELALEUCA ALTERNIFOLIA	A, E, H	Cineole is a mandatory component of Melaleuca alternifolia. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3243	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

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			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.
3244	MELALEUCA CITRINA	A, H	
3245	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.
3246	MELALEUCA ERICIFOLIA	A, E, H	Cineole is a mandatory component of Melaleuca ericifolia. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3247	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.
3248	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.

3249	MELALEUCA QUINQUENERVIA	A, E, H	Cineole is a mandatory component of Melaleuca quinquenervia. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3250	MELICOPE PTELEIFOLIA	A, H	
3251	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%.
3252	MELISSA OFFICINALIS	A, E, H	
3253	MELON	E	
3254	MENADIONE SODIUM BISULFITE	E	
3255	MENAQUINONE 7	A	For oral use only.

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			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.
3256	MENISPERMUM CANADENSE	A, H	
3257	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.
3258	MENTHA ARVENSIS	A, E, H	Menthol is a mandatory component of Mentha arvensis. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high

			concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3259	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.
3260	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:

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			- (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 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.
3262	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.

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	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.
3263	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.
3264	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.
3265	MENTHA X PIPERITA	A, E, H	Menthol is a mandatory component of Mentha x piperita. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:

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			– (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	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.
3267	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%.
3268	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%.
3269	MENTHOL	A, E	When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not

			deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3270	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%.

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3271	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%.
3272	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%.
3273	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3274	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%.
3275	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%.
3276	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).
3277	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%.
3278	MENTHYL LACTATE	E	
3279	MENYANTHES TRIFOLIATA	A, H	
3280	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient.
3281	MERCURY	H	Only for use as an active homoeopathic ingredient.
3282	METACRESOL	E	Only for use in topical medicines for dermal application.
3283	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3284	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%.

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3285	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%.
3286	METHIONINE	A, E	
3287	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%.
3288	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%.
3289	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%.
3290	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%.
3291	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%.
3292	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%.
3293	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3294	METHYL ANISATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3295	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

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			fragrance concentration in a medicine must be no more 1%.
3296	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3297	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%.
3298	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%.
3299	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%.
3300	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%.
3301	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%.
3302	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%.
3303	METHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3304	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%.
3305	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%.
3306	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%.
3307	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%.
3308	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%.
3309	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%.
3310	METHYL ETHER	E	Only for use in topical medicines for dermal

			application.
3311	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%.
3312	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%.
3313	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%.
3314	METHYL GLUCETH-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. Residue levels of ethylene oxide are to be kept below the level of detection.
3315	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.
3316	METHYL GLUCETH-20	E	Permitted for use only in

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	BENZOATE		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%.
3317	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3318	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3319	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3320	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3321	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%.
3322	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%.
3323	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%.
3324	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%.
3325	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%.
3326	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3327	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3328	METHYL HYDROXYBENZOATE	E	
3329	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

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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%.
3330	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%.
3331	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%.
3332	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%.
3333	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%.
3334	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%.
3335	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%.
3336	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%.
3337	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%.
3338	METHYL METHACRYLATE	E	
3339	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%.

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3340	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%.
3341	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%.
3342	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%.
3343	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%.
3344	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%.
3345	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%.
3346	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%.
3347	METHYL PHENYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3348	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%.
3349	METHYL PHENYL GLYCIDATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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			fragrance concentration in a medicine must be no more than 1%.
3350	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%.
3351	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%.
3352	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%.
3353	METHYL SALICYLATE	A, E	Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine

		requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25%; ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words

			to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
3354	METHYL STEARATE	E	
3355	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%.
3356	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%.
3357	METHYL-3-METHYLTHIOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3358	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%.

3359	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%.
3360	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%.
3361	METHYLCELLULOSE	A, E	
3362	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%.
3363	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%.
3364	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).
3365	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%.
3366	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%.
3367	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%.
3368	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%.

3369	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3370	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%.
3371	MICROCALICIUM ARENARIUM	A, H	
3372	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%.
3373	MICROCOS PANICULATA	A, H	
3374	MICROCRYSTALLINE CELLULOSE	E	
3375	MICROCRYSTALLINE WAX	E	Only for use as an excipient in medicines for topical, oral or oral application routes of administration. When microcrystalline wax is used as an excipient ingredient, the route of administration 'oral' is only permitted when the dosage form is 'chewing gum'.
3376	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

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			5%.
3377	MILK THISTLE FRUIT DRY	A, H	
3378	MILK THISTLE FRUIT POWDER	A, H	
3379	MILLET	E	
3380	MILLETTIA DIELSIANA	A, H	
3381	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%.
3382	MIMULUS GUTTATUS	A, H	
3383	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.
3384	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%.
3385	MITCHELLA REPENS	A, H	
3386	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3387	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3388	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%.
3389	MODIFIED FOOD STARCH	E	
3390	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

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			medicine must be no more than 5%.
3391	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.
3392	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.
3393	MOMORDICA BALSAMINA	A, H	
3394	MOMORDICA CHARANTIA	A, H	
3395	MOMORDICA COCHINCHINENSIS	A, H	
3396	MONARDA DIDYMA	A, H	
3397	MONO- AND DI- GLYCERIDES	E	
3398	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3399	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3400	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.
3401	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.
3402	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.
3403	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3404	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.
3405	MONOPHOSPHOTHIAMINE	A	
3406	MONOPHOSPHOTHIAMINE	A	

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	DIHYDRATE		
3407	MONOPOTASSIUM GLUTAMATE	A, E	
3408	MONOSODIUM DIHYDROGEN CITRATE	E	
3409	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	
3410	MONSTERA DELICIOSA	A, H	
3411	MONTAN WAX	E	
3412	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%..
3413	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).
3414	MORINDA OFFICINALIS	A, H	
3415	MORINGA OLEIFERA	A, H	
3416	MORUS ALBA	A, H	
3417	MORUS BOMBYCIS	A, H	
3418	MORUS NIGRA	A, E, H	
3419	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%.
3420	MOTHERWORT HERB DRY	A, H	
3421	MOTHERWORT HERB POWDER	A, H	
3422	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%.
3423	MULBERRY	E	
3424	MUNG BEAN	E	
3425	MURRAYA KOENIGII	A, H	
3426	MURRAYA PANICULATA	A, H	
3427	MUSA X PARADISIACA	A, H	
3428	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3429	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%.
3430	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3431	MUSKS	H	Only for use as an active homoeopathic ingredient.
3432	MUSTARD	E	Allyl isothiocyanate is a mandatory component of mustard when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3433	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%.

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3434	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%.
3435	MYOSOTIS ARVENSIS	A, H	
3436	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%.
3437	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%.
3438	MYRICA CERIFERA	A, E, H	
3439	MYRISTIC ACID	E	
3440	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%.

3441	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).
3442	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3443	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3444	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3445	MYROXYLON BALSAMUM	A, E, H	
3446	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3447	MYRRH	A, H	
3448	MYRRH OIL	A, E, H	
3449	MYRRH RESIN	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%.
3450	MYRRHIS ODORATA	A, H	
3451	MYRSINE AFRICANA	A, H	
3452	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%.
3453	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%.
3454	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%.
3455	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%.
3456	MYRTUS COMMUNIS	A, E, H	

3457	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.
3458	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%.
3459	N-GLUCONYL ETHANOLAMINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3460	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%.
3461	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

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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%.
3462	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3463	NARDOSTACHYS CHINENSIS	A, H	
3464	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%.
3465	NASTURTIUM OFFICINALE	A, E, H	
3466	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.
3467	NAUCLEA OFFICINALIS	A, H	
3468	NELUMBO NUCIFERA	A, H	
3469	NELUMBO NUCIFERA FLOWER WAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
3470	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%
3471	NEOMENTHOL	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3472	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%.
3473	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%.
3474	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.
3475	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3476	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3477	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%.
3478	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%.
3479	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%.
3480	NEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3481	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

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			1%.
3482	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%.
3483	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%.
3484	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%.
3485	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%.
3486	NICKEL	H	Only for use as an active homoeopathic ingredient.

3487	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3488	NICOTINAMIDE	A, E, H	
3489	NICOTINAMIDE ASCORBATE	A, E	
3490	NICOTINAMIDE RIBOSIDE CHLORIDE	A	Ribose is a mandatory component of nicotinamide riboside chloride. Only permitted for use in medicines limited to oral routes of administration. The maximum recommended daily dose of the medicine must not provide more than 300 mg of nicotinamide riboside chloride. The following warning statement (or words to the same effect) is required on the medicine label: - (NTAKEN12) 'Not to be taken by children under 12 years old.' When the maximum recommended daily dose of the medicine provides greater than 230 mg of nicotinamide riboside chloride, the following warning statement is required on the medicine label: - (PREG) 'Not recommended for use during pregnancy or lactation'.
3491	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.
3492	NIGELLA DAMASCENA	A, H	
3493	NIGELLA SATIVA	A, E, H	
3494	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3495	NONADIENOL	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%.
3496	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%.
3497	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%.
3498	NONFAT DRY MILK	E, H	
3499	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%.
3500	NONOXINOL 10	E	Only for use in topical medicines for dermal

			application.
3501	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%.
3502	NONOXINOL 5	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3503	NONOXINOL 9	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
3504	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%.
3505	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%.

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3506	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%.
3507	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%.
3508	NOTOPTERYGIUM FORBESII	A, H	
3509	NOTOPTERYGIUM INCISIUM	A, H	
3510	NUPHAR JAPONICA	A, H	
3511	NUPHAR LUTEA	A, H	
3512	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%.
3513	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).
3514	NUTMEG POWDER	A, E, H	Safrole is a mandatory component of Nutmeg powder. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
3515	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%.
3516	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%.
3517	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'.
3518	NYLON	E	Only for use in topical medicines for dermal application.
3519	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3520	NYLON-12	E	Only for use in topical medicines for dermal application.
3521	NYMPHAEA ALBA	A, E, H	
3522	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.
3523	NYMPHAEA ODORATA	A, H	
3524	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%.
3525	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%.
3526	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.
3527	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal.
3528	OATMEAL COLLOIDAL	A, E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal.
3529	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%.
3530	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%.
3531	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%.
3532	OCIMUM KILIMANDSCHARICUM	A, H	Camphor is a mandatory component of Ocimum kilimandscharicum. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. In essential oil or distillate preparations when the concentration of camphor is

			more than 2.5%, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must also have a child resistant closure fitted on the container.
3533	OCIMUM MINIMUM	A, H	
3534	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%.
3535	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%.
3536	OCTACOSANOL	E	
3537	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%.
3538	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3539	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%.
3540	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%.
3541	OCTAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3542	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%.
3543	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%.

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3544	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%.
3545	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%.
3546	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).
3547	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3548	OCTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3549	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.
3550	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3551	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%.
3552	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal

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			application.
3553	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).
3554	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3555	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).
3556	OCTYL STEARATE	E	Only for use in topical medicines for dermal

			application.
3557	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).
3558	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3559	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.
3560	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%.
3561	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
3562	OCTYLDODECYL STEARATE	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. The concentration in the medicine must be no more than 2%.
3563	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%.
3564	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%.
3565	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.
3566	OENANTHE CROCATA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3567	OENOTHERA BIENNIS	A, E, H	
3568	OENOTHERA STRICTA	A, H	
3569	OKOUBAKA AUBREVILLEI	A, H	
3570	OLDENLANDIA DIFFUSA	A, E, H	
3571	OLEA EUROPAEA	A, E, H	
3572	OLEIC ACID	E	
3573	OLETH-10	E	Only for use in topical medicines for dermal application.

3574	OLETH-2	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of Oleth-2. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3575	OLETH-20	E	Only for use in topical medicines for dermal application.
3576	OLETH-3	E	Only for use in topical medicines for dermal application.
3577	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%.
3578	OLETH-5	E	Only for use in topical medicines for dermal application.
3579	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3580	OLIBANUM OIL	A, E, H	
3581	OLIVE	E	
3582	OLIVE OIL	A, E, H	
3583	OMEGA-3 FISH OIL PHYTOSTEROL ESTERS	A	The medicine requires the following warning statement on the medicine label:

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			- (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'
3584	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).
3585	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.'
3586	ONION	E	
3587	ONION OIL	A, H	
3588	ONONIS SPINOSA	A, E, H	
3589	ONOPORDUM ACANTHIUM	A, H	
3590	ONOSMODIUM VIRGINIANUM	A, H	
3591	OPHIOPOGON JAPONICUS	A, H	
3592	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%.
3593	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

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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%.
3594	OPUNTIA FICUS-INDICA	A, H	
3595	ORANGE	E	
3596	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%.
3597	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.
3598	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%.
3599	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%.
3600	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.
3601	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.
3602	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:

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			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.
3603	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%.
3604	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.
3605	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%.
3606	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.

3607	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%.
3608	ORANGE PEEL DRIED BITTER	A, E, H	When used internally, oxedrine is a mandatory component of orange peel dried bitter. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3609	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%.
3610	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3611	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).
3612	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%.
3613	ORIGANUM OIL SPANISH	A, E, H	
3614	ORIGANUM VULGARE	A, E, H	
3615	ORNITHINE	A, E	
3616	ORNITHINE ASPARTATE	A, E	
3617	ORNITHINE MONOHYDROCHLORIDE	A, E	
3618	ORNITHOGALUM UMBELLATUM	A, H	
3619	OROSTACHYS FIMBRIATA	A, H	
3620	OROXYLUM INDICUM	A, H	
3621	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%.
3622	ORRIS CONCRETE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3623	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%.
3624	ORRIS ROOT OIL	A, E, H	
3625	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%.
3626	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%.

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3627	ORTHOSIPHON ARISTATUS	A, H	
3628	ORYZA SATIVA	A, E, H	
3629	ORYZANOL	E	
3630	OSBECKIA CHINENSIS	A, H	
3631	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%.
3632	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%.
3633	OTTELIA ALISMOIDES	A, H	
3634	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%.
3635	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3636	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%.

3637	OXALIC ACID	H	Only for use as an active homoeopathic ingredient.
3638	OXALIS ACETOSELLA	A, H	
3639	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%.
3640	OXIDISED TAPIOCA STARCH	E	
3641	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).
3642	OYSTER	E	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (a) The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc

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			products'.
3643	OYSTER SHELL	A, E, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (a) The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.