Volume 4

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**
2857	KADSURA COCCINEA	A, H	
2858	KAEMPFERIA GALANGA	A, H	
2859	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%.
2860	KAOLIN	E	
2861	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.
2862	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.
2863	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%.
2864	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%.
2865	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';

Volume 4

			- (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'.
2866	KIDNEY BEAN	E	
2867	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%.
2868	KIWI FRUIT	E	
2869	KNAUTIA ARVENSIS	A, H	
2870	KOREAN GINSENG ROOT DRY	A, H	
2871	KOREAN GINSENG ROOT POWDER	A, H	
2872	KRAMERIA IXIENA	A, H	
2873	KRAMERIA LAPPACEA	A, H	
2874	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'.
2875	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%.
2876	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%.
2877	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%.
2878	L-LIMONENE	E	L-limonene must only be

Volume 4

			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.
2879	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%.
2880	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%.
2881	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%.
2882	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%.
2883	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%.
2884	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%.
2885	LABDANUM OIL	A, E, H	
2886	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%.
2887	LACTALBUMIN	E	
2888	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.
2889	LACTITOL	E	
2890	LACTITOL MONOHYDRATE	E	
2891	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).
2892	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-

Volume 4

			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).
2893	LACTOBACILLUS ACIDOPHILUS	A	
2894	LACTOBACILLUS AMYLOVORUS	A	
2895	LACTOBACILLUS BREVIS	A	
2896	LACTOBACILLUS CASEI	A	
2897	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2898	LACTOBACILLUS CRISPATUS	A	
2899	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2900	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2901	LACTOBACILLUS FERMENTUM	A	
2902	LACTOBACILLUS GALLINARUM	A	
2903	LACTOBACILLUS GASSERI	A	
2904	LACTOBACILLUS HELVETICUS	A	
2905	LACTOBACILLUS JOHNSONII	A	
2906	LACTOBACILLUS KEFIRANOFACIENS	A	
2907	LACTOBACILLUS KEFIRGRANUM	A	
2908	LACTOBACILLUS KEFIRI	A	
2909	LACTOBACILLUS PARACASEI	A	
2910	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2911	LACTOBACILLUS PLANTARUM	A	
2912	LACTOBACILLUS REUTERI	A	
2913	LACTOBACILLUS RHAMNOSUS	A	
2914	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2915	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	

2916	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2917	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%.
2918	LACTOSE	E	
2919	LACTOSE MONOHYDRATE	E	
2920	LACTUCA SATIVA	A, H	
2921	LACTUCA VIROSA	A, H	
2922	LACTULOSE	E	
2923	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.
2924	LAGENARIA VULGARIS	A, H	
2925	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.
2926	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.
2927	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.
2928	LAMIUM ALBUM	A, H	
2929	LANETH-5	E	Only for use in topical medicines for dermal application.
2930	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2931	LANOLIN OIL	E	Only for use in topical medicines for dermal application.
2932	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2933	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material

			of Lantana camara.
2934	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%.
2935	LARIX DECIDUA	A, H	
2936	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.
2937	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'.
2938	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

Volume 4

			lathyrogenic amino acids.
2939	LAURAMINE OXIDE	E	
2940	LAUREL LEAF OIL	A, H	
2941	LAURETH-10	E	Only for use in topical medicines for dermal application.
2942	LAURETH-12	E	Only for use in topical medicines for dermal application.
2943	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.
2944	LAURETH-23	E	Only for use in topical medicines for dermal application.
2945	LAURETH-3	E	Only for use in topical medicines for dermal application.
2946	LAURETH-4	E	Only for use in topical medicines for dermal application.
2947	LAURETH-7	E	Only for use in topical medicines for dermal application.
2948	LAURETH-8	E	
2949	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.
2950	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%.
2951	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2952	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%.
2953	LAURUS NOBILIS	A, E, H	When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is less than or equal to 15 millilitres, a restricted flow insert must be fitted on the container. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is greater than 15 millilitres, a child resistant closure must be fitted on the container. When the concentration of Laurus nobilis oil or distillate in the preparation is greater

			than 25%, the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
2954	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%.
2955	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2956	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%.
2957	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.
2958	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%.
2959	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%.
2960	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%.
2961	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.
2962	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.
2963	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2964	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2965	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%.
2966	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2967	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%.
2968	LAVANDIN OIL ABRIAL	A, E, H	
2969	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%.
2970	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%.
2971	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%.
2972	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%.
2973	LAVENDER OIL	A, E, H	
2974	LAWSONIA INERMIS	A, H	
2975	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2976	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.

Volume 4

2977	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%.
2978	LECITHIN	A, E	
2979	LEDEBOURIELLA SESELOIDES	A, H	
2980	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.
2981	LEMNA MINOR	A, H	
2982	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.

2983	LEMON BALM LEAF DRY	A, H	
2984	LEMON BALM LEAF POWDER	A, E, H	
2985	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.
2986	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.
2987	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.
2988	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

Volume 4

			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2989	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.
2990	LEMONGRASS OIL	A, E, H	
2991	LENS CULINARIS	A, H	
2992	LENTIL	E	
2993	LENTINULA EDODES	A, E, H	
2994	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%.
2995	LEONURUS CARDIACA	A, E, H	
2996	LEONURUS SIBIRICUS	A, E, H	
2997	LEPIDIUM APETALUM	A, H	
2998	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).
2999	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.

3000	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’
3001	LESPEDEZA CAPITATA	A, H	
3002	LETTUCE	E	
3003	LEUCINE	A, E	
3004	LEUZEA UNIFLORUM	A, H	
3005	LEVISTICUM OFFICINALE	A, H	
3006	LEVOCARNITINE	A	
3007	LEVOCARNITINE FUMARATE	A	
3008	LEVOCARNITINE HYDROCHLORIDE	A	

Volume 4

3009	LEVOCARNITINE MAGNESIUM CITRATE	A	
3010	LEVOCARNITINE TARTRATE	A	
3011	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.
3012	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.
3013	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
3014	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%.
3015	LIGHT KAOLIN	E	
3016	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.
3017	LIGHT MAGNESIUM OXIDE	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of light magnesium oxide. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more

			total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3018	LIGUSTICUM SINENSE	A, H	
3019	LIGUSTICUM STRIATUM	A, E, H	
3020	LIGUSTRUM LUCIDUM	A, H	
3021	LILIUM BROWNII	A, H	
3022	LILIUM CANDIDUM	A, E, H	
3023	LILIUM LANCIFOLIUM	A, H	
3024	LILIUM LONGIFLORUM	A, H	
3025	LIME FRUIT	E	
3026	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%.
3027	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.
3028	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.
3029	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%.
3030	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%.
3031	LIME TREE FLOWER DRY	A, H	
3032	LIME TREE FLOWER POWDER	A, H	
3033	LIME, ESSENCE	E	
3034	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

Volume 4

			1%.
3035	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.
3036	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%.
3037	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%.
3038	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%.
3039	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%.
3040	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%.
3041	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%.
3042	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%.
3043	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%.

Volume 4

3044	LINALYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3045	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%.
3046	LINDERA STRYCHNIFOLIA	A, H	
3047	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%.
3048	LINOLEIC ACID	E	
3049	LINOLENIC ACID	E	
3050	LINSEED DRY	A, E, H	
3051	LINSEED OIL	A, E, H	
3052	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.
3053	LINSEED POWDER	A, E, H	
3054	LINUM USITATISSIMUM	A, E, H	
3055	LIPASE	A	Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline.
3056	LIPPIA DULCIS	A, H	
3057	LIQUID GLUCOSE	E	
3058	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.
3059	LIQUIDAMBAR FORMOSANA	A, H	
3060	LIQUIDAMBAR ORIENTALIS	A, H	
3061	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3062	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%.
3063	LIQUIDAMBAR TAIWANIANA	A, H	
3064	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%.

Volume 4

3065	LIQUORICE DRY	A, E, H	
3066	LIQUORICE LIQUID EXTRACT	A, E, H	
3067	LIQUORICE POWDER	A, E, H	
3068	LITCHI CHINENSIS	A, H	
3069	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
3070	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
3071	LITSEA CUBEBA	A, E, H	
3072	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%.
3073	LOBARIA PULMONARIA	A, H	
3074	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.
3075	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.
3076	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.

3077	LOLIUM PERENNE	A, H	
3078	LOLIUM TEMULENTUM	A, H	
3079	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%.
3080	LONICERA CAPRIFOLIUM	A, E, H	
3081	LONICERA JAPONICA	A, E, H	
3082	LONICERA PERICLYMENUM	A, H	
3083	LOPHATHERUM GRACILE	A, H	
3084	LOQUAT	E	
3085	LORANTHUS PARASITICUS	A, H	
3086	LOROPETALUM CHINENSIS	A, H	
3087	LOTUS CORNICULATUS	A, H	
3088	LOVAGE OIL	A, E, H	
3089	LOVAGE ROOT DRY	A, H	
3090	LOVAGE ROOT POWDER	A, H	
3091	LUDWIGIA PROSTRATA	A, H	
3092	LUFFA CYLINDRICA	A, H	
3093	LUFFA PURGANS	A, H	
3094	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.
3095	LYCHEE	E	
3096	LYCIUM BARBARUM	A, H	
3097	LYCIUM CHINENSE	A, E, H	
3098	LYCOPENE	A, E	
3099	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.

Volume 4

3100	LYCOPODIUM ANNOTINUM	A, H	
3101	LYCOPODIUM CLAVATUM	A, H	
3102	LYCOPODIUM COMPLANATUM	A, H	
3103	LYCOPUS EUROPAEUS	A, H	
3104	LYCOPUS LUCIDUS	A, H	
3105	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%.
3106	LYGODIUM JAPONICUM	A, H	
3107	LYSIMACHIA CHRISTINAE	A, H	
3108	LYSIMACHIA VULGARIS	A, H	
3109	LYSINE	A, E	
3110	LYSINE HYDROCHLORIDE	A, E	
3111	LYTHRUM HYSSOPIFOLIA	A, H	
3112	LYTHRUM SALICARIA	A, H	
3113	LYTHRUM VERTICILLATUM	A, H	
3114	MACADAMIA INTEGRIFOLIA	A, E	
3115	MACADAMIA NUT	E	
3116	MACADAMIA NUT OIL	E	
3117	MACADAMIA TERNIFOLIA	A, E, H	
3118	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%.
3119	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.
3120	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.
3121	MACROGOL 1000	E	
3122	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3123	MACROGOL 1500	E	
3124	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%.
3125	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3126	MACROGOL 20000	E	
3127	MACROGOL 300	E	

Volume 4

3128	MACROGOL 3000	E	
3129	MACROGOL 3350	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time.
3130	MACROGOL 40	E	Only for use in topical medicines for dermal application.
3131	MACROGOL 400	E	
3132	MACROGOL 4000	E	
3133	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3134	MACROGOL 600	E	
3135	MACROGOL 6000	E	
3136	MACROGOL 600000	E	
3137	MACROGOL 800	E	
3138	MACROGOL 8000	E	
3139	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%.
3140	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3141	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3142	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.
3143	MAGNESIUM ASCORBATE	A, E, H	
3144	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	
3145	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3146	MAGNESIUM ASPARTATE	A, E, H	
3147	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3148	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3149	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3150	MAGNESIUM CHLORIDE 4.5-HYDRATE	A	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium chloride 4.5-hydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or

			(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3151	MAGNESIUM CHLORIDE HEXAHYDRATE	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium chloride hexahydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more

			total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3152	MAGNESIUM CITRATE	A, E, H	
3153	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	
3154	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	
3155	MAGNESIUM DIGLUTAMATE	A, E, H	
3156	MAGNESIUM GLUCONATE	A, E, H	
3157	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3158	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.
3159	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.
3160	MAGNESIUM HYDROGEN PHOSPHATE	H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022.

Volume 4

			(a) Magnesium is a mandatory component of magnesium hydrogen phosphate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3161	MAGNESIUM HYDROXIDE	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.

	The requirements specified in paragraph (a) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2021; - released for supply before or on 1 March 2022; and - the following warning statement is not specified on the label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (a) When the medicine is not promoted or marketed as laxative, contains more than 2 g magnesium hydroxide per maximum recommended daily dose, the following warning statements are required on the label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect'. The requirements specified in paragraphs (b) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (b) Magnesium is a mandatory component of magnesium hydroxide. (c) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for:

Volume 4

			(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (d) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3162	MAGNESIUM LYSINATE	A	Only for use in oral medicines.
3163	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3164	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3165	MAGNESIUM OROTATE	A, E, H	
3166	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3167	MAGNESIUM OXIDE	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022.

			(a) Magnesium is a mandatory component of magnesium oxide. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3168	MAGNESIUM PHOSPHATE PENTAHYDRATE	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium

Volume 4

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

			contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (b) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3170	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.
3171	MAGNESIUM STEARATE	E	
3172	MAGNESIUM SULFATE	A, E, H	When used internally, the

Volume 4

	DIHYDRATE	maximum recommended daily dose must not be more than 1.5g. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium sulfate dihydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.

3173	MAGNESIUM SULFATE HEPTAHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5 g. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium sulfate heptahydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (c) When the route of administration is oral, the medicine must not be directed

Volume 4

			for use in infants younger than 12 months of age.
3174	MAGNESIUM SULFATE MONOHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5 g. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium sulfate monohydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (c) When the route of

			administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3175	MAGNESIUM SULFATE TRIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5 g. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium sulfate trihydrate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that

			effect). (c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3176	MAGNESIUM TRISILICATE	E	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of magnesium trisilicate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and (iii) where the maximum recommended daily dose for: (A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). (c) When the route of

			administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3177	MAGNOLIA GLAUCA	A, H	
3178	MAGNOLIA LILIFLORA	A, H	
3179	MAGNOLIA OBOVATA	A, H	
3180	MAGNOLIA OFFICINALIS	A, E, H	
3181	MAGNOLIA SALICIFOLIA	A, H	
3182	MAIZE	E	
3183	MAIZE BRAN	E	
3184	MAIZE OIL	A, E, H	
3185	MAIZE STARCH	A, E, H	
3186	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3187	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.
3188	MALPIGHIA GLABRA	A, E, H	
3189	MALT EXTRACT	E	
3190	MALTITOL	E	
3191	MALTITOL SOLUTION	E	
3192	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.
3193	MALTOL	E	
3194	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%.

Volume 4

3195	MALTOSE	E	
3196	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
3197	MALUS SYLVESTRIS	A, H	
3198	MALVA MOSCHATA	A, H	
3199	MALVA SYLVESTRIS	A, E, H	
3200	MALVA VERTICILLATA	A, H	
3201	MANDARIN	E	
3202	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%.
3203	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.
3204	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%.
3205	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%.
3206	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%.
3207	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%.
3208	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3209	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3210	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3211	MANGANESE ACETATE	H	Only for use as an active

Volume 4

	TETRAHYDRATE		homoeopathic ingredient.
3212	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.
3213	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3214	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.
3215	MANGANESE GLUCONATE	A, E, H	
3216	MANGANESE GLYCEROPHOSPHATE	A, E, H	
3217	MANGANESE OXIDE	A, E, H	
3218	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3219	MANGANESE SULFATE TETRAHYDRATE	A, E, H	
3220	MANGIFERA INDICA	A, E, H	
3221	MANGO	E, H	
3222	MANIHOT ESCULENTA	A, H	
3223	MANNITOL	E	
3224	MARANTA ARUNDINACEA	A, H	
3225	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3226	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).
3227	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).
3228	MARRUBIUM VULGARE	A, E, H	
3229	MARSDENIA CUNDURANGO	A, H	
3230	MARSHMALLOW ROOT DRY	A, H	
3231	MARSHMALLOW ROOT POWDER	A, H	
3232	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%.
3233	MASTIC	A, H	
3234	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%.
3235	MATRICARIA CHAMOMILLA	A, E, H	
3236	MATRICARIA FLOWER DRY	A, E, H	
3237	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'.
3238	MECOBALAMIN (CO-METHYLCOBALAMIN)	A	Only for use in oral medicines.
3239	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.
3240	MEDIUM CHAIN TRIGLYCERIDES	E	
3241	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:

Volume 4

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

3243	MELALEUCA CITRINA	A, H	
3244	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.
3245	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

Volume 4

			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 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.
3247	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.
3248	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:

Volume 4

			- (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3249	MELICOPE PTELEIFOLIA	A, H	
3250	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%.
3251	MELISSA OFFICINALIS	A, E, H	
3252	MELON	E	
3253	MENADIONE SODIUM BISULFITE	E	
3254	MENAQUINONE 7	A	For oral use only. The medicine must not provide more than 180 micrograms per maximum daily dose in adults, 90 micrograms per maximum daily dose in children between 10-18 years, and 45 micrograms per maximum daily dose in children less than 10 years of age.
3255	MENISPERMUM CANADENSE	A, H	
3256	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.
3257	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;

Volume 4

			(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 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

Volume 4

			recommended daily dose must not contain more than 1 gram of menthol.
3259	MENTHA ARVENSIS OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%. Menthol is a mandatory component of Mentha arvensis oil. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statements is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the

			following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3260	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.
3261	MENTHA PULEGIUM	A, H	D-pulegone, menthol and volatile oil components (of Mentha pulegium) are mandatory components of Mentha pulegium. When the nominal capacity of the container is more than 15 millilitres, the concentration of d-pulegone in the medicine must be no more than 4%. When the concentration of d-pulegone in the preparation is more than 4% and the nominal capacity of the container is 15 millilitres or less, the medicine must have a child resistant closure and restricted flow insert fitted on the container. The medicine requires the following warning statements on the medicine label: - (NTAKEN) 'Not to be taken'; - (CHILD) 'Keep out of reach of children' (or words to that effect). When the medicine is for topical use for dermal application: a) the maximum recommended daily dose must not contain more than 150 mg of Mentha pulegium oil or distillate; b) the medicine must not be intended for use in the eye or on damaged skin; c) the medicine must not deliver more than 25% total

			menthol when administered according to the directions for use; d) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). e) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. f) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use: a) the maximum recommended daily dose must not contain more than 50 mg of Mentha pulegium oil or distillate; b) the maximum recommended daily dose must not contain more than 1 gram of menthol.
3262	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.
3263	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.
3264	MENTHA X PIPERITA	A, E, H	Menthol is a mandatory component of Mentha x piperita. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin;

			(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3265	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.
3266	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%.
3267	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%.
3268	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;

Volume 4

			- (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.
3269	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%.
3270	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%.
3271	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%.

3272	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3273	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%.
3274	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%.
3275	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).
3276	MENTHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Volume 4

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3277	MENTHYL LACTATE	E	
3278	MENYANTHES TRIFOLIATA	A, H	
3279	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient.
3280	MERCURY	H	Only for use as an active homoeopathic ingredient.
3281	METACRESOL	E	Only for use in topical medicines for dermal application.
3282	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3283	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%.
3284	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%.
3285	METHIONINE	A, E	
3286	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%.

3287	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%.
3288	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%.
3289	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%.
3290	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%.
3291	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

Volume 4

			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3292	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3293	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%.
3294	METHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3295	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3296	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%.
3297	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%.
3298	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%.
3299	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%.
3300	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%.
3301	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

Volume 4

			excipient formulation in a medicine must be no more than 1%.
3302	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%.
3303	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%.
3304	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%.
3305	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%.
3306	METHYL DI-TERT-BUTYL-4-	E	Permitted for use only in

	HYDROXYHYDROCINNAMATE		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 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%.
3308	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%.
3309	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3310	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%.
3311	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

Volume 4

			medicine must be no more 1%.
3312	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%.
3313	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.
3314	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.
3315	METHYL GLUCETH-20 BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3316	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3317	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3318	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.

3319	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3320	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%.
3321	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%.
3322	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%.
3323	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%.

Volume 4

3324	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%.
3325	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3326	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3327	METHYL HYDROXYBENZOATE	E	
3328	METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3329	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%.
3330	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%.
3331	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%.
3332	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%.
3333	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%.
3334	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%.
3335	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

Volume 4

			medicine must be no more than 1%.
3336	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%.
3337	METHYL METHACRYLATE	E	
3338	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%.
3339	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%.
3340	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%.
3341	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%.
3342	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%.
3343	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%.
3344	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%.
3345	METHYL PALMITATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Volume 4

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3346	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%.
3347	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%.
3348	METHYL PHENYL GLYCIDATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3349	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%.
3350	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%.
3351	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%.
3352	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.

Volume 4

			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'.
3353	METHYL STEARATE	E	
3354	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%.

3355	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%.
3356	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%.
3357	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%.
3358	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%.
3359	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%.
3360	METHYLCELLULOSE	A, E	

Volume 4

3361	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%.
3362	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%.
3363	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).
3364	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%.

3365	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%.
3366	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%.
3367	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%.
3368	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3369	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%.
3370	MICROCALICIUM ARENARIUM	A, H	
3371	MICROCOCCUS LUTEUS LYSATE	E	Only for use in topical medicines for dermal application and not to be

Volume 4

			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
3372	MICROCOS PANICULATA	A, H	
3373	MICROCRYSTALLINE CELLULOSE	E	
3374	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'.
3375	MILK FAT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3376	MILK THISTLE FRUIT DRY	A, H	
3377	MILK THISTLE FRUIT POWDER	A, H	
3378	MILLET	E	
3379	MILLETTIA DIELSIANA	A, H	
3380	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%.
3381	MIMULUS GUTTATUS	A, H	
3382	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.
3383	MINTLACTONE	E	Permitted for use only in combination with other permitted ingredients as a

Volume 4

			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3384	MITCHELLA REPENS	A, H	
3385	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3386	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3387	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%.
3388	MODIFIED FOOD STARCH	E	
3389	MOLASSES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3390	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.
3391	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.
3392	MOMORDICA BALSAMINA	A, H	
3393	MOMORDICA CHARANTIA	A, H	
3394	MOMORDICA COCHINCHINENSIS	A, H	
3395	MONARDA DIDYMA	A, H	
3396	MONO- AND DI- GLYCERIDES	E	
3397	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3398	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3399	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.
3400	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.
3401	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.
3402	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3403	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.
3404	MONOPHOSPHOTHIAMINE	A	
3405	MONOPHOSPHOTHIAMINE DIHYDRATE	A	
3406	MONOPOTASSIUM GLUTAMATE	A, E	
3407	MONOSODIUM DIHYDROGEN CITRATE	E	
3408	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	
3409	MONSTERA DELICIOSA	A, H	
3410	MONTAN WAX	E	
3411	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%..
3412	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).
3413	MORINDA OFFICINALIS	A, H	
3414	MORINGA OLEIFERA	A, H	
3415	MORUS ALBA	A, H	
3416	MORUS BOMBYCIS	A, H	
3417	MORUS NIGRA	A, E, H	
3418	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%.
3419	MOTHERWORT HERB DRY	A, H	
3420	MOTHERWORT HERB POWDER	A, H	
3421	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%.
3422	MULBERRY	E	
3423	MUNG BEAN	E	
3424	MURRAYA KOENIGII	A, H	
3425	MURRAYA PANICULATA	A, H	
3426	MUSA X PARADISIACA	A, H	
3427	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3428	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

Volume 4

			medicine must be no more than 1%.
3429	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3430	MUSKS	H	Only for use as an active homoeopathic ingredient.
3431	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%.
3432	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%.
3433	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%.
3434	MYOSOTIS ARVENSIS	A, H	
3435	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%.
3436	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%.
3437	MYRICA CERIFERA	A, E, H	
3438	MYRISTIC ACID	E	
3439	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%.
3440	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).
3441	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3442	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3443	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3444	MYROXYLON BALSAMUM	A, E, H	
3445	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3446	MYRRH	A, H	
3447	MYRRH OIL	A, E, H	
3448	MYRRH RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3449	MYRRHIS ODORATA	A, H	
3450	MYRSINE AFRICANA	A, H	
3451	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%.
3452	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%.
3453	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%.
3454	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%.
3455	MYRTUS COMMUNIS	A, E, H	
3456	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.
3457	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

Volume 4

			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3458	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%.
3459	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%.
3460	N-NONYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3461	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3462	NARDOSTACHYS CHINENSIS	A, H	
3463	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%.
3464	NASTURTIUM OFFICINALE	A, E, H	
3465	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.
3466	NAUCLEA OFFICINALIS	A, H	
3467	NELUMBO NUCIFERA	A, H	
3468	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%.
3469	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%
3470	NEOMENTHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3471	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%.

3472	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%.
3473	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.
3474	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3475	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3476	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%.
3477	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%.

Volume 4

3478	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%.
3479	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%.
3480	NEROL OXIDE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3481	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%.
3482	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%.
3483	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%.
3484	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%.
3485	NICKEL	H	Only for use as an active homoeopathic ingredient.
3486	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3487	NICOTINAMIDE	A, E, H	
3488	NICOTINAMIDE ASCORBATE	A, E	
3489	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

Volume 4

			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'.
3490	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.
3491	NIGELLA DAMASCENA	A, H	
3492	NIGELLA SATIVA	A, E, H	
3493	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3494	NONADIENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3495	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%.
3496	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%.
3497	NONFAT DRY MILK	E, H	
3498	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%.
3499	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3500	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%.
3501	NONOXINOL 5	E	Permitted for use only in combination with other

Volume 4

			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3502	NONOXINOL 9	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
3503	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%.
3504	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%.
3505	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%.
3506	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%.
3507	NOTOPTERYGIUM FORBESII	A, H	
3508	NOTOPTERYGIUM INCISIUM	A, H	
3509	NUPHAR JAPONICA	A, H	
3510	NUPHAR LUTEA	A, H	
3511	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%.
3512	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).
3513	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

Volume 4

			0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
3514	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%.
3515	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%.
3516	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'.

Volume 4

3517	NYLON	E	Only for use in topical medicines for dermal application.
3518	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3519	NYLON-12	E	Only for use in topical medicines for dermal application.
3520	NYMPHAEA ALBA	A, E, H	
3521	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.
3522	NYMPHAEA ODORATA	A, H	
3523	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%.
3524	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%.

3525	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.
3526	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal.
3527	OATMEAL COLLOIDAL	A, E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal.
3528	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%.
3529	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%.
3530	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%.
3531	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

Volume 4

			must also have a child resistant closure fitted on the container.
3532	OCIMUM MINIMUM	A, H	
3533	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%.
3534	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%.
3535	OCTACOSANOL	E	
3536	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%.
3537	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3538	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%.
3539	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%.
3540	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%.
3541	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%.
3542	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%.
3543	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%.
3544	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%.
3545	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).
3546	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3547	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

Volume 4

			medicine must be no more 1%.
3548	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.
3549	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3550	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%.
3551	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3552	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).
3553	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3554	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).
3555	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.
3556	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).
3557	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3558	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.
3559	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%.
3560	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
3561	OCTYLDODECYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3562	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%.
3563	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%.
3564	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.
3565	OENANTHE CROCATA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3566	OENOTHERA BIENNIS	A, E, H	
3567	OENOTHERA STRICTA	A, H	
3568	OKOUBAKA AUBREVILLEI	A, H	
3569	OLDENLANDIA DIFFUSA	A, E, H	
3570	OLEA EUROPAEA	A, E, H	
3571	OLEIC ACID	E	
3572	OLETH-10	E	Only for use in topical medicines for dermal application.
3573	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%.
3574	OLETH-20	E	Only for use in topical medicines for dermal

Volume 4

			application.
3575	OLETH-3	E	Only for use in topical medicines for dermal application.
3576	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%.
3577	OLETH-5	E	Only for use in topical medicines for dermal application.
3578	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3579	OLIBANUM OIL	A, E, H	
3580	OLIVE	E	
3581	OLIVE OIL	A, E, H	
3582	OMEGA-3 FISH OIL PHYTOSTEROL ESTERS	A	The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'
3583	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).
3584	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

Volume 4

			recommended.'
3585	ONION	E	
3586	ONION OIL	A, H	
3587	ONONIS SPINOSA	A, E, H	
3588	ONOPORDUM ACANTHIUM	A, H	
3589	ONOSMODIUM VIRGINIANUM	A, H	
3590	OPHIOPOGON JAPONICUS	A, H	
3591	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%.
3592	OPOPANAX OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3593	OPUNTIA FICUS-INDICA	A, H	
3594	ORANGE	E	
3595	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%.
3596	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.
3597	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%.
3598	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%.
3599	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.
3600	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

Volume 4

			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.
3601	ORANGE OIL BITTER COLDPRESSED	A, E, H	When used internally, oxedrine is a mandatory component of orange oil bitter coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 1.4% or less of orange oil bitter coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.
3602	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%.
3603	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.
3604	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%.
3605	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.
3606	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%.
3607	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.

Volume 4

3608	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%.
3609	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3610	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).
3611	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%.
3612	ORIGANUM OIL SPANISH	A, E, H	
3613	ORIGANUM VULGARE	A, E, H	
3614	ORNITHINE	A, E	
3615	ORNITHINE ASPARTATE	A, E	
3616	ORNITHINE MONOHYDROCHLORIDE	A, E	
3617	ORNITHOGALUM UMBELLATUM	A, H	
3618	OROSTACHYS FIMBRIATA	A, H	
3619	OROXYLUM INDICUM	A, H	
3620	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%.
3621	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%.

Volume 4

3622	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%.
3623	ORRIS ROOT OIL	A, E, H	
3624	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%.
3625	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%.
3626	ORTHOSIPHON ARISTATUS	A, H	
3627	ORYZA SATIVA	A, E, H	
3628	ORYZANOL	E	
3629	OSBECKIA CHINENSIS	A, H	
3630	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%.
3631	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%.
3632	OTTELIA ALISMOIDES	A, H	
3633	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%.
3634	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3635	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%.
3636	OXALIC ACID	H	Only for use as an active homoeopathic ingredient.
3637	OXALIS ACETOSELLA	A, H	
3638	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%.
3639	OXIDISED TAPIOCA STARCH	E	
3640	OXYBENZONE	A	Only for use as an active ingredient in sunscreens for

Volume 4

			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).
3641	OYSTER	E	
3642	OYSTER SHELL	A, E, H	