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**
2833	KADSURA COCCINEA	A, H	
2834	KAEMPFERIA GALANGA	A, H	
2835	KALMIA LATIFOLIA	A, H	Arbutin is a mandatory component of Kalmia latifolia. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
2836	KAOLIN	E	
2837	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.
2838	KELP POWDER	A, E, H	Iodine is a mandatory component of Kelp powder. Only for external use when the

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
2839	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%.
2840	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%.
2841	KHAYA SENEGALENSIS	A, E	Only to be used in a medicine where Bioactive Solutions Pty Ltd (Client ID 61631), 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 27 September 2020.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The maximum daily dose of the medicine must not contain more than the equivalent of 1g dry bark of Khaya senegalensis. The following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'; - (LONGUSE) ‘Not for prolonged use. May harm liver'; - (GEN2) ‘If symptoms persist, seek the advice of a healthcare professional’; - (CHILD3) ‘Use in children under 12 years is not recommended’; and - (7DAYS) 'Do not use for more than 7 days'.
2842	KIDNEY BEAN	E	
2843	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%.
2844	KIWI FRUIT	E	
2845	KNAUTIA ARVENSIS	A, H	
2846	KOREAN GINSENG ROOT DRY	A, H	

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2847	KOREAN GINSENG ROOT POWDER	A, H	
2848	KRAMERIA IXIENA	A, H	
2849	KRAMERIA LAPPACEA	A, H	
2850	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'.
2851	L-BORNEOL	E	Permitted for use only in

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2852	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%.
2853	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%.
2854	L-LIMONENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2855	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%.
2856	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%.
2857	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%.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2858	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%.
2859	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%.
2860	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%.
2861	LABDANUM OIL	A, E, H	
2862	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%.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2863	LACTALBUMIN	E	
2864	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.
2865	LACTITOL	E	The medicine requires the following warning statements on the medicine label: - (SUGOLS) 'Medicines containing lactitol may have a laxative effect or cause diarrhoea' (or words to that effect); - (LACT) 'Contains lactose' (or words to that effect); and - (COWMK) 'Derived from cows milk'.
2866	LACTITOL MONOHYDRATE	E	The medicine requires the following warning statements on the medicine label: - (SUGOLS) 'Medicines containing lactitol monohydrate may have a laxative effect or cause

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			diarrhoea' (or words to that effect) - (LACT) 'Contains lactose' (or words to that effect) - (COWMK) 'Derived from cows milk'.
2867	LACTOBACILLUS ACIDOPHILUS	A	
2868	LACTOBACILLUS AMYLOVORUS	A	
2869	LACTOBACILLUS BREVIS	A	
2870	LACTOBACILLUS CASEI	A	
2871	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2872	LACTOBACILLUS CRISPATUS	A	
2873	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2874	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2875	LACTOBACILLUS FERMENTUM	A	
2876	LACTOBACILLUS GALLINARUM	A	
2877	LACTOBACILLUS GASSERI	A	
2878	LACTOBACILLUS HELVETICUS	A	
2879	LACTOBACILLUS JOHNSONII	A	
2880	LACTOBACILLUS KEFIRANOFACIENS	A	
2881	LACTOBACILLUS KEFIRGRANUM	A	
2882	LACTOBACILLUS KEFIRI	A	
2883	LACTOBACILLUS PARACASEI	A	
2884	LACTOBACILLUS PARACASEI	A	

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	SUBSP. PARACASEI		
2885	LACTOBACILLUS PLANTARUM	A	
2886	LACTOBACILLUS REUTERI	A	
2887	LACTOBACILLUS RHAMNOSUS	A	
2888	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2889	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2890	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2891	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%.
2892	LACTOSE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars [or words to that effect]’ if medicine

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose [or words to that effect]'.
2893	LACTOSE MONOHYDRATE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose monohydrate, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars [or words to that effect]' if medicine contains two or more sugars. If one of the sugars is lactose monohydrate then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose monohydrate [or words to that effect]'.
2894	LACTUCA SATIVA	A, H	
2895	LACTUCA VIROSA	A, H	

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2896	LACTULOSE	E	
2897	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.
2898	LAGENARIA VULGARIS	A, H	
2899	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.
2900	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			dose.
2901	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.
2902	LAMIUM ALBUM	A, H	
2903	LANETH-5	E	Only for use in topical medicines for dermal application.
2904	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2905	LANOLIN OIL	E	Only for use in topical medicines for dermal application.
2906	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2907	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			equivalent dry herbal material of Lantana camara.
2908	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%.
2909	LARIX DECIDUA	A, H	
2910	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.
2911	LARREA TRIDENTATA	A, H	The medicine requires the following warning statement on the medicine label: - (CHAP) 'WARNING: Chaparral may harm the liver

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			in some people - use only under supervision of a health care professional'.
2912	LATHYRUS SATIVUS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lathyrus sativus. The medicine must not contain lathyrogenic amino acids.
2913	LAURAMINE OXIDE	E	
2914	LAUREL LEAF OIL	A, H	
2915	LAURETH-10	E	Only for use in topical medicines for dermal application.
2916	LAURETH-12	E	Only for use in topical medicines for dermal application.
2917	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.
2918	LAURETH-23	E	Only for use in topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
2919	LAURETH-3	E	Only for use in topical medicines for dermal application.
2920	LAURETH-4	E	Only for use in topical medicines for dermal application.
2921	LAURETH-7	E	Only for use in topical medicines for dermal application.
2922	LAURETH-8	E	
2923	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.
2924	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%.
2925	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2926	LAUROYL LYSINE	E	Only for use in topical

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2927	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'.
2928	LAURYL ALDEHYDE	E	Permitted for use only in

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2929	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2930	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%.
2931	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			finished medicine is safe for its intended purpose.
2932	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%.
2933	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%.
2934	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%.
2935	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			9%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
2936	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.
2937	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2938	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2939	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%.
2940	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2941	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%.
2942	LAVANDIN OIL ABRIAL	A, E, H	
2943	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%.
2944	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%.
2945	LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia subsp. angustifolia.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2946	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%.
2947	LAVENDER OIL	A, E, H	
2948	LAWSONIA INERMIS	A, H	
2949	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2950	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.
2951	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%.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2952	LECITHIN	A, E	
2953	LEDEBOURIELLA SESELOIDES	A, H	
2954	LEDUM GROENLANDICUM	A, H	
2955	LEDUM PALUSTRE	A, H	Arbutin is a mandatory component of Ledum palustre. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %. When the route of administration is other than topical, the maximum recommended daily dose must not contain more than 0.001mg of the equivalent dry herbal material of Ledum palustre.
2956	LEMNA MINOR	A, H	
2957	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.
2958	LEMON BALM LEAF DRY	A, H	
2959	LEMON BALM LEAF POWDER	A, E, H	
2960	LEMON OIL	A, E, H	When used internally, oxedrine is a mandatory component of lemon oil.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
2961	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.
2962	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.
2963	LEMON OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2964	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.
2965	LEMONGRASS OIL	A, E, H	
2966	LENS CULINARIS	A, H	
2967	LENTIL	E	
2968	LENTINULA EDODES	A, E, H	
2969	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%.
2970	LEONURUS CARDIACA	A, E, H	
2971	LEONURUS SIBIRICUS	A, E, H	
2972	LEPIDIUM APETALUM	A, H	
2973	LEPIDIUM MEYENII	A	Only for use in oral medicines when the plant part is tuber and

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2974	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.
2975	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'
2976	LESPEDEZA CAPITATA	A, H	
2977	LETTUCE	E	
2978	LEUCINE	A, E	
2979	LEUZEA UNIFLORUM	A, H	
2980	LEVISTICUM OFFICINALE	A, H	
2981	LEVOCARNITINE	A	
2982	LEVOCARNITINE FUMARATE	A	
2983	LEVOCARNITINE HYDROCHLORIDE	A	
2984	LEVOCARNITINE MAGNESIUM CITRATE	A	
2985	LEVOCARNITINE TARTRATE	A	
2986	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,

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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. When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects the following warning statement is required on the medicine label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'.
2987	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.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects the following warning statement is required on the medicine label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect).'
2988	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
2989	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%.
2990	LIGHT KAOLIN	E	
2991	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.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2992	LIGHT MAGNESIUM OXIDE	A, E, H	
2993	LIGUSTICUM SINENSE	A, H	
2994	LIGUSTICUM STRIATUM	A, E, H	
2995	LIGUSTRUM LUCIDUM	A, H	
2996	LILIUM BROWNII	A, H	
2997	LILIUM CANDIDUM	A, E, H	
2998	LILIUM LANCIFOLIUM	A, H	
2999	LILIUM LONGIFLORUM	A, H	
3000	LIME FRUIT	E	
3001	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%.
3002	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.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3003	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.
3004	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%.
3005	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%.
3006	LIME TREE FLOWER DRY	A, H	
3007	LIME TREE FLOWER POWDER	A, H	
3008	LIME, ESSENCE	E	
3009	LIMES TERPENES	E	Permitted for use only in

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
3010	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.
3011	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%.
3012	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%.
3013	LINALYL ACETAL	E	Permitted for use only in combination with other

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3014	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%.
3015	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%.
3016	LINALYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more than 1%.
3017	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%.
3018	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%.
3019	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%.
3020	LINALYL PROPIONATE	E	Permitted for use only in

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3021	LINDERA STRYCHNIFOLIA	A, H	
3022	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%.
3023	LINOLEIC ACID	E	
3024	LINOLENIC ACID	E	
3025	LINSEED DRY	A, E, H	
3026	LINSEED OIL	A, E, H	
3027	LINSEED POWDER	A, E, H	
3028	LINUM USITATISSIMUM	A, E, H	
3029	LIPASE	A	Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline When used in an undivided preparation, the unit 'Thousand lipase units per gram' is permitted. When used in a divided

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			preparation, the unit 'Thousand lipase unit' is permitted.
3030	LIPPIA DULCIS	A, H	
3031	LIQUID GLUCOSE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
3032	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.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3033	LIQUIDAMBAR FORMOSANA	A, H	
3034	LIQUIDAMBAR ORIENTALIS	A, H	
3035	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3036	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%.
3037	LIQUIDAMBAR TAIWANIANA	A, H	
3038	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%.
3039	LIQUORICE DRY	A, E, H	
3040	LIQUORICE LIQUID EXTRACT	A, E, H	
3041	LIQUORICE POWDER	A, E, H	
3042	LITCHI CHINENSIS	A, H	
3043	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
3044	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3045	LITSEA CUBEBA	A, E, H	
3046	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%.
3047	LOBARIA PULMONARIA	A, H	
3048	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.
3049	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.
3050	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.
3051	LOLIUM PERENNE	A, H	
3052	LOLIUM TEMULENTUM	A, H	
3053	LONGIFOLENE	E	Permitted for use only in

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
3054	LONICERA CAPRIFOLIUM	A, E, H	
3055	LONICERA JAPONICA	A, E, H	
3056	LONICERA PERICLYMENUM	A, H	
3057	LOPHATHERUM GRACILE	A, H	
3058	LOQUAT	E	
3059	LORANTHUS PARASITICUS	A, H	
3060	LOROPETALUM CHINENSIS	A, H	
3061	LOTUS CORNICULATUS	A, H	
3062	LOVAGE OIL	A, E, H	
3063	LOVAGE ROOT DRY	A, H	
3064	LOVAGE ROOT POWDER	A, H	
3065	LUDWIGIA PROSTRATA	A, H	
3066	LUFFA CYLINDRICA	A, H	
3067	LUFFA PURGANS	A, H	
3068	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.
3069	LYCHEE	E	
3070	LYCIUM BARBARUM	A, H	
3071	LYCIUM CHINENSE	A, E, H	

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3072	LYCOPENE	A, E	
3073	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.
3074	LYCOPODIUM ANNOTINUM	A, H	
3075	LYCOPODIUM CLAVATUM	A, H	
3076	LYCOPODIUM COMPLANATUM	A, H	
3077	LYCOPUS EUROPAEUS	A, H	
3078	LYCOPUS LUCIDUS	A, H	
3079	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%.
3080	LYGODIUM JAPONICUM	A, H	
3081	LYSIMACHIA CHRISTINAE	A, H	
3082	LYSIMACHIA VULGARIS	A, H	
3083	LYSINE	A, E	
3084	LYSINE HYDROCHLORIDE	A, E	
3085	LYTHRUM HYSSOPIFOLIA	A, H	
3086	LYTHRUM SALICARIA	A, H	
3087	LYTHRUM VERTICILLATUM	A, H	
3088	MACADAMIA INTEGRIFOLIA	A, E	
3089	MACADAMIA NUT	E	

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3090	MACADAMIA NUT OIL	E	
3091	MACADAMIA TERNIFOLIA	A, E, H	
3092	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%.
3093	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.
3094	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
3095	MACROGOL 1000	E	
3096	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3097	MACROGOL 1500	E	
3098	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%.
3099	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3100	MACROGOL 20000	E	
3101	MACROGOL 300	E	
3102	MACROGOL 3000	E	
3103	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			substance monograph of the British Pharmacopoeia, as in force or existing form time to time.
3104	MACROGOL 40	E	Only for use in topical medicines for dermal application.
3105	MACROGOL 400	E	
3106	MACROGOL 4000	E	
3107	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3108	MACROGOL 600	E	
3109	MACROGOL 6000	E	
3110	MACROGOL 600000	E	
3111	MACROGOL 800	E	
3112	MACROGOL 8000	E	
3113	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%.
3114	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3115	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3116	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.
3117	MAGNESIUM ASCORBATE	A, E, H	
3118	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	
3119	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3120	MAGNESIUM ASPARTATE	A, E, H	
3121	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3122	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3123	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3124	MAGNESIUM CHLORIDE 4.5-HYDRATE	A	
3125	MAGNESIUM CHLORIDE HEXAHYDRATE	A, E, H	
3126	MAGNESIUM CITRATE	A, E, H	
3127	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	
3128	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	
3129	MAGNESIUM DIGLUTAMATE	A, E, H	
3130	MAGNESIUM GLUCONATE	A, E, H	

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3131	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3132	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.
3133	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.
3134	MAGNESIUM HYDROGEN PHOSPHATE	H	
3135	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. 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)]'

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (LAX4) 'This product may have laxative effect'.
3136	MAGNESIUM LYSINATE	A	Only for use in oral medicines.
3137	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3138	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3139	MAGNESIUM OROTATE	A, E, H	
3140	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3141	MAGNESIUM OXIDE	A, E, H	
3142	MAGNESIUM PHOSPHATE PENTAHYDRATE	A, E, H	
3143	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.
3144	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.
3145	MAGNESIUM STEARATE	E	
3146	MAGNESIUM SULFATE DIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1.5g.
3147	MAGNESIUM SULFATE HEPTAHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3148	MAGNESIUM SULFATE MONOHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3149	MAGNESIUM SULFATE TRIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3150	MAGNESIUM TRISILICATE	E	
3151	MAGNOLIA GLAUCA	A, H	
3152	MAGNOLIA LILIFLORA	A, H	
3153	MAGNOLIA OBOVATA	A, H	
3154	MAGNOLIA OFFICINALIS	A, E, H	
3155	MAGNOLIA SALICIFOLIA	A, H	
3156	MAIZE	E	
3157	MAIZE BRAN	E	
3158	MAIZE OIL	A, E, H	
3159	MAIZE STARCH	A, E, H	
3160	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3161	MALIC ACID	E	Sponsors should consider the impact of excipients on the sensitivity of the skin to

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			sunlight and should ensure the finished medicine is safe for its intended purpose.
3162	MALPIGHIA GLABRA	A, E, H	
3163	MALT EXTRACT	E	
3164	MALTITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]'.
3165	MALTITOL SOLUTION	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea' (or words to that effect).

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3166	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.
3167	MALTOL	E	
3168	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%.
3169	MALTOSE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (LACT) ‘Contains lactose' (or words to that effect).
3170	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
3171	MALUS PUMILA	A, E, H	A medicine that contains the ingredient must not be listed in the Register on or after 2 March 2020 or be supplied after 2 March 2021.
3172	MALUS SYLVESTRIS	A, H	
3173	MALVA MOSCHATA	A, H	
3174	MALVA SYLVESTRIS	A, E, H	
3175	MALVA VERTICILLATA	A, H	
3176	MANDARIN	E	
3177	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%.
3178	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			milligrams.
3179	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%.
3180	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%.
3181	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%.
3182	MANDRAGORA OFFICINARUM	A, H	Atropine, hyoscine and hyoscyamine are mandatory components of Mandragora officinarum. The concentration in the medicine must be no more than

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
3183	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3184	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3185	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3186	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3187	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.
3188	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3189	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3190	MANGANESE GLUCONATE	A, E, H	
3191	MANGANESE GLYCEROPHOSPHATE	A, E, H	
3192	MANGANESE OXIDE	A, E, H	
3193	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3194	MANGANESE SULFATE TETRAHYDRATE	A, E, H	
3195	MANGIFERA INDICA	A, E, H	
3196	MANGO	E, H	
3197	MANIHOT ESCULENTA	A, H	
3198	MANNITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea' (or words to that effect).
3199	MARANTA ARUNDINACEA	A, H	
3200	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3201	MARJORAM OIL SPANISH	A, E, H	When the concentration in the preparation is more than 50%, the nominal capacity of the

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
3202	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).
3203	MARRUBIUM VULGARE	A, E, H	
3204	MARSDENIA CUNDURANGO	A, H	
3205	MARSHMALLOW ROOT DRY	A, H	
3206	MARSHMALLOW ROOT POWDER	A, H	
3207	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%.
3208	MASTIC	A, H	

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3209	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%.
3210	MATRICARIA CHAMOMILLA	A, E, H	
3211	MATRICARIA FLOWER DRY	A, E, H	
3212	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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);

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
3213	MECOBALAMIN (CO-METHYLCOBALAMIN)	A	Only for use in oral medicines.
3214	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.
3215	MEDIUM CHAIN TRIGLYCERIDES	E	
3216	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3217	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'.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3218	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3219	MELALEUCA ERICIFOLIA	A, E, H	Cineole is a mandatory component of Melaleuca ericifolia. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3220	MELALEUCA LINARIIFOLIA	A, H	Cineole is a mandatory

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3221	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3222	MELALEUCA QUINQUENERVIA	A, E, H	Cineole is a mandatory component of Melaleuca quinquenervia. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3223	MELICOPE PTELEIFOLIA	A, H	
3224	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%.
3225	MELISSA OFFICINALIS	A, E, H	
3226	MELON	E	
3227	MENADIONE SODIUM BISULFITE	E	
3228	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.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3229	MENISPERMUM CANADENSE	A, H	
3230	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3231	MENTHA ARVENSIS	A, E, H	Menthol is a mandatory component of Mentha arvensis. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops,

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3232	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3233	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,

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3234	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3235	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3236	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3237	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3238	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:

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			– (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.
3239	MENTHADIENYL 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%.
3240	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%.
3241	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%.
3242	MENTHOL	A, E	When the medicine is for

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			recommended daily dose must not contain more than 1 gram of menthol.
3243	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%.
3244	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%.
3245	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%.
3246	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3247	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%.
3248	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%.
3249	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).

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3250	MENTHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3251	MENTHYL LACTATE	E	
3252	MENYANTHES TRIFOLIATA	A, H	
3253	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient.
3254	MERCURY	H	Only for use as an active homoeopathic ingredient.
3255	MESPILUS GERMANICA	A, H	
3256	METACRESOL	E	Only for use in topical medicines for dermal application.
3257	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3258	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%.
3259	METHICONE	E	Only for use in topical medicines for dermal application and not to be

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
3260	METHIONINE	A, E	
3261	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%.
3262	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%.
3263	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more 1%.
3264	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%.
3265	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%.
3266	METHYL ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3267	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3268	METHYL ANISATE	E	Permitted for use only in combination with other permitted ingredients as a

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3269	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%.
3270	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3271	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%.
3272	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
3273	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%.
3274	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%.
3275	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%.
3276	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in medicines intended for oral use. The quantity of methyl chavicol in a medicine must be no more than 0.01%. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3277	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%.
3278	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%.
3279	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3280	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%.
3281	METHYL DI-TERT-BUTYL-4-HYDROXYHYDROCINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3282	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%.
3283	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
3284	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3285	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%.
3286	METHYL EUGENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3287	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%.
3288	METHYL GLUCETH-10	E	Only for use in topical medicines for dermal application and not to be

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3289	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.
3290	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%.
3291	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3292	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3293	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3294	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3295	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%.
3296	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%.
3297	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%.
3298	METHYL HEXYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3299	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%.
3300	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3301	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3302	METHYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect)

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			if product contains one hydroxybenzoate source.
3303	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%.
3304	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%.
3305	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%.
3306	METHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%.
3307	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%.
3308	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%.
3309	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%.
3310	METHYL LINOLENATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
3311	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%.
3312	METHYL METHACRYLATE	E	
3313	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%.
3314	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%.
3315	METHYL MYRISTATE	E	Permitted for use only in combination with other

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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 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%.
3317	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%.
3318	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

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
3319	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%.
3320	METHYL PALMITATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3321	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%.
3322	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
3323	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%.
3324	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%.
3325	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%.
3326	METHYL ROSINATE	E	Permitted for use only in combination with other

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3327	METHYL SALICYLATE	A, E	Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. The following warning statement is required on the

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
3328	METHYL STEARATE	E	

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3329	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%.
3330	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%.
3331	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%.
3332	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%.
3333	METHYL-PARA-TERT-BUTYL PHENYLACETATE	E	Permitted for use only in combination with other

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3334	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%.
3335	METHYLCELLULOSE	A, E	
3336	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%.
3337	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%.
3338	METHYLDIBROMO GLUTARONITRILE	E	Only for use in topical medicines for dermal

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
3339	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).
3340	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%.
3341	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
3342	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%.
3343	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%.
3344	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3345	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%.
3346	MICROCALICIUM ARENARIUM	A, H	
3347	MICROCOCCUS LUTEUS	E	Only for use in topical

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	LYSATE		medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
3348	MICROCOS PANICULATA	A, H	
3349	MICROCRYSTALLINE CELLULOSE	E	
3350	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'.
3351	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%.
3352	MILK THISTLE FRUIT DRY	A, H	
3353	MILK THISTLE FRUIT POWDER	A, H	
3354	MILLET	E	
3355	MILLETTIA DIELSIANA	A, H	
3356	MIMOSA ABSOLUTE	E	Permitted for use only in

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with 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	MIMULUS GUTTATUS	A, H	
3358	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;

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (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.
3359	MINTLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3360	MITCHELLA REPENS	A, H	
3361	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3362	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3363	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1%.
3364	MODIFIED FOOD STARCH	E	
3365	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%.
3366	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.
3367	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			molecular weight of molybdenum trioxide.
3368	MOMORDICA BALSAMINA	A, H	
3369	MOMORDICA CHARANTIA	A, H	
3370	MOMORDICA COCHINCHINENSIS	A, H	When Lycopene, Lutein or Betocarotene are declared as components, the plant part is restricted to fruit flesh, fruit peel or seed aril.
3371	MONARDA DIDYMA	A, H	
3372	MONO- AND DI- GLYCERIDES	E	
3373	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3374	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3375	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.
3376	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
3377	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. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
3378	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application. The concentration in the medicine must be no more than 5%.
3379	MONOPHOSPHOTHIAMINE	A	
3380	MONOPHOSPHOTHIAMINE DIHYDRATE	A	
3381	MONOPOTASSIUM GLUTAMATE	A, E	
3382	MONOSODIUM DIHYDROGEN CITRATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
3383	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	
3384	MONSTERA DELICIOSA	A, H	
3385	MONTAN WAX	E	
3386	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%..
3387	MORINDA CITRIFOLIA	A, H	Only for use when the plant part is fruit and the plant preparation is fruit juice or fruit

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			powder. Fruit powder must be produced by freeze drying the whole fruit (excluding the seeds).
3388	MORINDA OFFICINALIS	A, H	
3389	MORINGA OLEIFERA	A, H	
3390	MORUS ALBA	A, H	
3391	MORUS BOMBYCIS	A, H	
3392	MORUS NIGRA	A, E, H	
3393	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%.
3394	MOTHERWORT HERB DRY	A, H	
3395	MOTHERWORT HERB POWDER	A, H	
3396	MUCUNA PRURIENS	A, H	Levodopa (of Mucuna pruriens) is a mandatory component of Mucuna pruriens. The concentration of Levodopa (of Mucuna pruriens) in the medicine must be no more than 1mg/kg or 1mg/L or 0.1%.
3397	MULBERRY	E	
3398	MUNG BEAN	E	
3399	MURRAYA KOENIGII	A, H	
3400	MURRAYA PANICULATA	A, H	

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3401	MUSA X PARADISIACA	A, H	
3402	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3403	MUSK TIBETENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3404	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3405	MUSKS	H	Only for use as an active homoeopathic ingredient.
3406	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%.
3407	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3408	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%.
3409	MYOSOTIS ARVENSIS	A, H	
3410	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%.
3411	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%.
3412	MYRICA CERIFERA	A, E, H	

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3413	MYRISTIC ACID	E	
3414	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%.
3415	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).

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3416	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3417	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3418	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3419	MYROXYLON BALSAMUM	A, E, H	
3420	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3421	MYRRH	A, H	
3422	MYRRH OIL	A, E, H	
3423	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%.
3424	MYRRHIS ODORATA	A, H	
3425	MYRSINE AFRICANA	A, H	
3426	MYRTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3427	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%.
3428	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%.
3429	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%.
3430	MYRTUS COMMUNIS	A, E, H	
3431	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3432	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%.
3433	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%.
3434	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%.
3435	NAPHTHALENE	H	Only for use as an active

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			homoeopathic ingredient.
3436	NARDOSTACHYS CHINENSIS	A, H	
3437	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%.
3438	NASTURTIUM OFFICINALE	A, E, H	
3439	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3440	NAUCLEA OFFICINALIS	A, H	
3441	NELUMBO NUCIFERA	A, H	
3442	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%.
3443	NEOHESPERIDIN-	E	Only for use in topical

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	DIHYDROCHALCONE		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%
3444	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%.
3445	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%.
3446	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%.
3447	NEOPENTYL GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3448	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3449	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3450	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%.
3451	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%.
3452	NERIUM OLEANDER	A, H	The concentration of equivalent dry Nerium oleander in the product must be

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			no more than 1mg/Kg or 1mg/L or 0.0001%.
3453	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%.
3454	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%.
3455	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3456	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%.
3457	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%.
3458	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%.
3459	NICKEL	H	Only for use as an active homoeopathic ingredient.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3460	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3461	NICOTINAMIDE	A, E, H	
3462	NICOTINAMIDE ASCORBATE	A, E	
3463	NICOTINAMIDE RIBOSIDE CHLORIDE	A	Only to be used in a medicine where Chromadex Inc (Client ID 68566), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 02 December 2021. Ribose is a mandatory component of Nicotinamide riboside chloride. Only permitted for use in medicines limited to oral routes of administration. The maximum recommended daily dose of the medicine must not contain more than 300mg of Nicotinamide riboside chloride. The following warning statement is required on the medicine label: - (CHILD3) ‘Not for use in children under the age of 12’. When the maximum recommended daily dose of the medicine provides greater than 230mg of nicotinamide

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			riboside chloride, the following warning statement is required on the medicine label: - (PREG) 'Not recommended for use during pregnancy or lactation'.
3464	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.
3465	NIGELLA DAMASCENA	A, H	
3466	NIGELLA SATIVA	A, E, H	
3467	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3468	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%.
3469	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

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more 1%.
3470	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%.
3471	NONFAT DRY MILK	E, H	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
3472	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%.
3473	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3474	NONOXINOL 12	E	For use in hand scrub formulations for healthcare

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
3475	NONOXINOL 5	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3476	NONOXINOL 9	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
3477	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%.
3478	NOOTKATONE	E	Permitted for use only in combination with other permitted ingredients as a

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3479	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%.
3480	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%.
3481	NOTOPTERYGIUM FORBESII	A, H	
3482	NOTOPTERYGIUM INCISIUM	A, H	
3483	NUPHAR JAPONICA	A, H	
3484	NUPHAR LUTEA	A, H	
3485	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			must be no more than 1%.
3486	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).
3487	NUTMEG POWDER	A, E, H	Safrole is a mandatory component of Nutmeg powder. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
3488	NUX VOMICA DRY	A, H	Strychnine (of Strychnos spp.) is a mandatory component of

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Nux Vomica Dry. The concentration of in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3489	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%.
3490	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
3491	NYLON	E	Only for use in topical medicines for dermal application.
3492	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3493	NYLON-12	E	Only for use in topical medicines for dermal application.
3494	NYMPHAEA ALBA	A, E, H	
3495	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.
3496	NYMPHAEA ODORATA	A, H	

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3497	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%.
3498	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%.
3499	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.
3500	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal.
3501	OATMEAL COLLOIDAL	A, E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			topical and mucosal.
3502	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%.
3503	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%.
3504	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
3505	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'.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must also have a child resistant closure fitted on the container.
3506	OCIMUM MINIMUM	A, H	
3507	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

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
3508	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%.
3509	OCTACOSANOL	E	
3510	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%.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3511	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3512	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%.
3513	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%.
3514	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%.
3515	OCTANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3516	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%.
3517	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%.

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3518	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%.
3519	OCTHILINONE	E	Only for use in topical medicines for dermal application.
3520	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).
3521	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3522	OCTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3523	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3524	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%.
3525	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3526	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
3527	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3528	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).
3529	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3530	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).
3531	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3532	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.
3533	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%.
3534	OCTYLDODECYL	E	Only for use in topical

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	NEOPENTANOATE		medicines for dermal application.
3535	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%.
3536	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%.
3537	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%.
3538	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.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3539	OENANTHE CROCATA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3540	OENOTHERA BIENNIS	A, E, H	
3541	OENOTHERA STRICTA	A, H	
3542	OKOUBAKA AUBREVILLEI	A, H	
3543	OLDENLANDIA DIFFUSA	A, E, H	
3544	OLEA EUROPAEA	A, E, H	
3545	OLEIC ACID	E	
3546	OLETH-10	E	Only for use in topical medicines for dermal application.
3547	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%.
3548	OLETH-20	E	Only for use in topical medicines for dermal application.
3549	OLETH-3	E	Only for use in topical medicines for dermal

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
3550	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%.
3551	OLETH-5	E	Only for use in topical medicines for dermal application.
3552	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3553	OLIBANUM OIL	A, E, H	
3554	OLIGOFRUCTOSE	A, E	
3555	OLIVE	E	
3556	OLIVE OIL	A, E, H	
3557	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).'
3558	OMEGA-3-ACID ETHYL ESTERS 60	A	Docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid are mandatory components of omega-3-acid ethyl esters 60.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Only to be used in a medicine where DSM Nutritional Products Pty Ltd (Client ID 31685), 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 30 June 2021. 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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			food' (or words to that effect).
3559	OMEGA-3-ACID ETHYL ESTERS 90	A	Only for use in oral medicines. The maximum recommended daily dose must not exceed 4000 mg of Omega-3-acid ethyl esters 90, AND must not provide more than 3750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids. The medicine requires the following warning statements on the medicine label: - 'Individuals taking anticoagulants should seek medical advice before taking this product' (or words to that effect). -'To be taken with food' (or words to that effect). - 'Not recommended for used by pregnant and lactating women' (or words to that effect). - 'Use in children under 12 years is not recommended' (or words to that effect).
3560	ONION	E	
3561	ONION OIL	A, H	
3562	ONONIS SPINOSA	A, E, H	
3563	ONOPORDUM ACANTHIUM	A, H	
3564	ONOSMODIUM VIRGINIANUM	A, H	
3565	OPHIOPOGON JAPONICUS	A, H	

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3566	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%.
3567	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%.
3568	OPUNTIA FICUS-INDICA	A, H	
3569	ORANGE	E	
3570	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

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more 1%.
3571	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.
3572	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%.
3573	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%.
3574	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.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3575	ORANGE OIL BITTER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavor, the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' or words to that effect must be include on the medicine label unless the medicine is: a) for internal use; b) in preparations containing 1.4% or less of orange oil bitter; c) for use in soaps or bath or shower gels that are washed off the skin.
3576	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:

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
3577	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%.
3578	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.
3579	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

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
3580	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.
3581	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%.
3582	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.
3583	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%.

Authorised Version F2020L00150 registered 20/02/2020

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3584	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3585	ORIGANUM MAJORANA	A, H	Arbutin is a mandatory component of Origanum majorana. The concentration of arbutin in the medicine must be no more than 25mg/Kg or 25mg/L or 0.0025% unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74%. When the plant preparation is oil or distillate and the concentration of Origanum majoranum oil or distillate within the medicine is greater than 50%: a) the nominal capacity of the container must be no more than 50 millilitre; b) a restricted flow insert must be fitted on the container; and c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3586	ORIGANUM OIL	E	Permitted for use only in combination with other ingredients as a fragrance.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used as a fragrance the total concentration in the medicine must be no more than 1%.
3587	ORIGANUM OIL SPANISH	A, E, H	
3588	ORIGANUM VULGARE	A, E, H	
3589	ORNITHINE	A, E	
3590	ORNITHINE ASPARTATE	A, E	
3591	ORNITHINE MONOHYDROCHLORIDE	A, E	
3592	ORNITHOGALUM UMBELLATUM	A, H	
3593	OROSTACHYS FIMBRIATA	A, H	
3594	OROXYLUM INDICUM	A, H	
3595	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%.
3596	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%.
3597	ORRIS ROOT EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3598	ORRIS ROOT OIL	A, E, H	
3599	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%.
3600	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%.
3601	ORTHOSIPHON ARISTATUS	A, H	
3602	ORYZA SATIVA	A, E, H	
3603	ORYZANOL	E	
3604	OSBECKIA CHINENSIS	A, H	
3605	OSMANTHUS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2020L00150 registered 20/02/2020

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

Volume 4

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3606	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%.
3607	OTTELIA ALISMOIDES	A, H	
3608	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%.
3609	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3610	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%.
3611	OXALIC ACID	H	Only for use as an active

Authorised Version F2020L00150 registered 20/02/2020

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			homoeopathic ingredient.
3612	OXALIS ACETOSELLA	A, H	
3613	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%.
3614	OXIDISED TAPIOCA STARCH	E	
3615	OXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3616	OYSTER	E	
3617	OYSTER SHELL	A, E, H	

Authorised Version F2020L00150 registered 20/02/2020