Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2016

made under subsection 26BB(1) of the

Therapeutic Goods Act 1989

Compilation No. 1

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Volume 1: section 1–3, Schedule 1, Parts 1 and 2 (items 1–714)
Volume 2: Schedule 1, Part 2 (items 715–2122)
Volume 3: Schedule 1, Part 2 (items 2123—2761)
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Each volume has its own contents

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About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2016* that shows the text of the law as amended and in force on 6 October 2016 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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

(section 4)

Part 2—Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2762	KADSURA COCCINEA	A,H	
2763	KAEMPFERIA GALANGA	A,H	
2764	KALMIA LATIFOLIA	A,H	
2765	KAOLIN	E	
2766	KAOLIN - HEAVY	E	
2767	KAOLIN - LIGHT	E	
2768	KELP DRY	A,H	Iodine is a mandatory component of Kelp dry. Only for external use when the concentration of available iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
2769	KELP POWDER	A,E,H	Iodine is a mandatory component of Kelp powder. Only for external use when the

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			concentration of available iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2770	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%.
2771	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%.
2772	KIDNEY BEAN	E	
2773	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%.
2774	KIWI FRUIT	E	
2775	KNAUTIA ARVENSIS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2776	KOREAN GINSENG ROOT DRY	A,H	
2777	KOREAN GINSENG ROOT POWDER	A,H	
2778	KRAMERIA IXIENA	A,H	
2779	KRAMERIA LAPPACEA	A,H	
2780	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'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2781	L-BORNEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2782	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%.
2783	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%.
2784	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2785	L-LINALOOL	E	Permitted for use only in combination with

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2786	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%.
2787	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%.
2788	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%.
2789	LABDANUM ABSOLUTE	E	Permitted for use only in combination with

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2790	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%.
2791	LABDANUM OIL	A,E,H	
2792	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%.
2793	LACTALBUMIN	E	
2794	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 Pharmacopeia. 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.
2795	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 diarrhoea' (or words to that effect) - (LACT) 'Contains lactose' (or words to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			that effect) - (COWMK) 'Derived from cows milk'.
2796	LACTOBACILLUS ACIDOPHILUS	A	
2797	LACTOBACILLUS AMYLOVORUS	A	
2798	LACTOBACILLUS BREVIS	A	
2799	LACTOBACILLUS CASEI	A	
2800	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2801	LACTOBACILLUS CRISPATUS	A	
2802	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2803	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2804	LACTOBACILLUS FERMENTUM	A	
2805	LACTOBACILLUS GALLINARUM	A	
2806	LACTOBACILLUS GASSERI	A	
2807	LACTOBACILLUS HELVETICUS	A	
2808	LACTOBACILLUS JOHNSONII	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2809	LACTOBACILLUS KEFIRANOFACIENS	A	
2810	LACTOBACILLUS KEFIRGRANUM	A	
2811	LACTOBACILLUS KEFIRI	A	
2812	LACTOBACILLUS PARACASEI	A	
2813	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2814	LACTOBACILLUS PLANTARUM	A	
2815	LACTOBACILLUS REUTERI	A	
2816	LACTOBACILLUS RHAMNOSUS	A	
2817	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2818	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2819	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2820	LACTOFERRIN - BOVINE	A	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from cow's milk.'
2821	LACTOSCATONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance

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			concentration in a medicine must be no more than 1%.
2822	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 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]'.
2823	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

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			medicine label: - (LACT) 'Contains lactose monohydrate [or words to that effect]'.
2824	LACTUCA SATIVA	A,H	
2825	LACTUCA VIROSA	A,H	
2826	LACTULOSE	E	
2827	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 Pharmacopeia.
2828	LAGENARIA VULGARIS	A,H	
2829	LAMINARIA CLOUSTONI	A,E,H	Iodine is a mandatory component of Laminaria cloustoni. Only for external use when the concentration of available iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2830	LAMINARIA DIGITATA	A,E,H	Iodine is a mandatory component of Laminaria japonica and must be declared in the application. Only for external use when the concentration of available iodine in the

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			medicine (excluding salts derivatives or iodophors) is more than 2.5%. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2831	LAMINARIA JAPONICA	A,E,H	Iodine is a mandatory component of Laminaria japonica. Only for external use when the concentration of available iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2832	LAMIUM ALBUM	A,H	
2833	LANETH-5	E	Only for use in topical medicines for dermal application.
2834	LANOLIN - HYDROXYLATED	E	
2835	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2836	LANOLIN OIL	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application.
2837	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2838	LANTANA CAMARA	A,H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.
2839	LARIX DECIDUA	A,H	
2840	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.
2841	LARREA TRIDENTATA	A,H	The medicine requires the following warning statement on the medicine label: - (CHAP) 'WARNING: Chaparral may harm the liver in some people - use only under supervision of a health care professional'.
2842	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.
2843	LAURAMINE OXIDE	E	
2844	LAUREL LEAF OIL	A,H	
2845	LAURETH-10	E	Only for use in topical medicines for dermal application.
2846	LAURETH-12	E	Only for use in topical medicines for dermal application.

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2847	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.
2848	LAURETH-23	E	Only for use in topical medicines for dermal application.
2849	LAURETH-3	E	Only for use in topical medicines for dermal application.
2850	LAURETH-4	E	Only for use in topical medicines for dermal application.
2851	LAURETH-7	E	Only for use in topical medicines for dermal application.
2852	LAURETH-8	E	
2853	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.
2854	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%.
2855	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2856	LAUROYL LYSINE	E	Only for use in topical medicines for dermal application and not to be included

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.75%.
2857	LAURUS NOBILIS	A,E,H	
2858	LAURYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2859	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2860	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%.
2861	LAURYL LACTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. Sponsors should consider the impact of excipients containing alpha hydroxy acids on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose.

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2862	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%.
2863	LAURYL PEG-10 TRIS(TRIMETHYLSILOXY)SILYLETHYL 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%.
2864	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. The concentration in the medicine must be no more than 2.5%.
2865	LAURYL PEG/PPG-18/18 METHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 9%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
2866	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.
2867	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2868	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2869	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%.
2870	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2871	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%.
2872	LAVANDIN OIL ABRIAL	A,E,H	
2873	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%.
2874	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

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			oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil 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 have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			(or words to that effect); and - (NTAKEN) 'Not to be taken'.
2875	LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA	A,E,H	
2876	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%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, 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'

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			(or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil 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 have a restricted flow insert and child resistant closure 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'.
2877	LAVENDER OIL	A,E,H	Camphor is a mandatory component of lavender oil. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil 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 have a restricted flow insert and child resistant closure 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'.
2878	LAWSONIA INERMIS	A,H	
2879	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2880	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.
2881	LEAF ACETAL	E	Permitted for use only in combination with

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			other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
2882	LECITHIN	A,E	
2883	LECITHIN - EGG	A,E	
2884	LECITHIN - HYDROGENATED	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%.
2885	LECITHIN LIQUID - SOY PHOSPHATIDYLSERINE-ENRICHED SOY	A	Soy phosphatidylserine is a mandatory component of Lecithin liquid - soy phosphatidylserine-enriched soy. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
2886	LECITHIN POWDER - SOY PHOSPHATIDYLSERINE-ENRICHED SOY	A	Soy phosphatidylserine is a mandatory component of Lecithin powder - soy phosphatidylserine-enriched soy. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
2887	LEDEBOURIELLA SESELOIDES	A,H	
2888	LEDUM GROENLANDICUM	A,H	
2889	LEDUM PALUSTRE	A,H	When the route of administration is other than topical, the maximum recommended daily dose must be no more than 0.001mg of the equivalent dry herbal material of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Ledum palustre.
2890	LEMNA MINOR	A,H	
2891	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.
2892	LEMON BALM LEAF DRY	A,H	
2893	LEMON BALM LEAF POWDER	A,E,H	
2894	LEMON OIL	A,E,H	When used internally, oxedrine is a mandatory component of lemon oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) steam distilled or rectified; or b) for internal use; or c) contains 0.05% or less of lemon oil; or d) for use in soaps or bath or shower gels that are washed off the skin.
2895	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

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			recommended daily dose must be no more than 30 milligrams.
2896	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.
2897	LEMON OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2898	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.
2899	LEMONGRASS OIL	A,E,H	
2900	LENS CULINARIS	A,H	
2901	LENTIL	E	
2902	LENTINULA EDODES	A,E,H	
2903	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 1%.
2904	LEONURUS CARDIACA	A,E,H	
2905	LEONURUS SIBIRICUS	A,E,H	
2906	LEPIDIUM APETALUM	A,H	
2907	LEPIDIUM MEYENII	A	Only for use in oral medicines when the plant part is tuber and the plant preparation is dry. The maximum recommended daily dose must be no more than 3.5g of Lepidium meyenii dried tuber (or its extract equivalent).
2908	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.
2909	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’

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When the concentration is more than 25%, the nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
2910	LESPEDEZA CAPITATA	A,H	
2911	LETTUCE	E	
2912	LEUCINE	A,E	
2913	LEUZEA UNIFLORUM	A,H	
2914	LEVISTICUM OFFICINALE	A,H	
2915	LEVOCARNITINE	A	
2916	LEVOCARNITINE FUMARATE	A	
2917	LEVOCARNITINE HYDROCHLORIDE	A	
2918	LEVOCARNITINE MAGNESIUM CITRATE	A	
2919	LEVOCARNITINE TARTRATE	A	
2920	LEVOMEFOLATE CALCIUM	A,H	Only for use in oral medicines. Levomefolic acid is a mandatory component of Levomefolate calcium. The maximum recommended daily dose

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must provide no more than 500mcg of Levomefolic acid from Levomefolate calcium. When used in combination with folic acid, folinic acid and/or their derivatives, the medicine must not provide more than a total of 500 mcg of folic acid, folinic acid and/or their derivatives in total per maximum recommended daily dose. The following indication is only permitted when the medicine is for oral use and the required warning statement '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)' is included on the medicine label. - Provides a minimum daily dose of 400-500micrograms of folic acid or folate. If taken daily when trying to conceive and during the first trimester of pregnancy and/or for at least four weeks before conception and during the first trimester of pregnancy, folic acid may help to prevent neural tube defects such as spina bifida and/or anencephaly. [Warning NEUR required]
2921	LEVOMEFOLATE GLUCOSAMINE	A	Only for use in oral medicines. Levomefolic acid is a mandatory component of Levomefolate glucosamine. The maximum recommended daily dose must provide no more than 500mcg of Levomefolic acid from Levomefolate glucosamine. When used in combination with folic acid, folinic acid and/or their derivatives, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must not provide more than a total of 500 mcg of folic acid, folinic acid and/or their derivatives in total per maximum recommended daily dose. The following indication is only permitted when the medicine is for oral use and the required warning statement '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)' is included on the medicine label. - Provides a minimum daily dose of 400-500 micrograms of folic acid or folate. If taken daily when trying to conceive and during the first trimester of pregnancy and/or for at least four weeks before conception and during the first trimester of pregnancy, folic acid may help to prevent neural tube defects such as spina bifida and/or anencephaly. [Warning NEUR required]
2922	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
2923	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%.
2924	LIGUSTICUM SINENSE	A,H	
2925	LIGUSTICUM WALLICHII	A,E,H	
2926	LIGUSTRUM LUCIDUM	A,H	
2927	LILIUM BROWNII	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2928	LILIUM CANDIDUM	A,E,H	
2929	LILIUM LANCIFOLIUM	A,H	
2930	LILIUM LONGIFLORUM	A,H	
2931	LIME FRUIT	E	
2932	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%.
2933	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.
2934	LIME OIL DISTILLED	A,E,H	
2935	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2936	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%.
2937	LIME TREE FLOWER DRY	A,H	
2938	LIME TREE FLOWER POWDER	A,H	
2939	LIME, ESSENCE	E	
2940	LIMES TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2941	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.
2942	LINALOOL	E	Only for use in topical medicines for dermal application.
2943	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more 1%.
2944	LINALYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2945	LINALYL ACETATE	E	Only for use in topical medicines for dermal application.
2946	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%.
2947	LINALYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2948	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%.
2949	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2950	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%.
2951	LINALYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2952	LINDERA STRYCHNIFOLIA	A,H	
2953	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%.
2954	LINOLEIC ACID	E	
2955	LINOLENIC ACID	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2956	LINSEED DRY	A,E,H	
2957	LINSEED OIL	A,E,H	
2958	LINSEED POWDER	A,E,H	
2959	LINUM USITATISSIMUM	A,E,H	
2960	LIPASE	A	Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline When used in an undvided preparation, the unit 'Thousand lipase units per gram' is permitted. When used in a divuded preparation, the unit 'Thousand lipase unit' is permitted.
2961	LIQUIDAMBAR FORMOSANA	A,H	
2962	LIQUIDAMBAR ORIENTALIS	A,H	
2963	LIQUIDAMBAR STYRACIFLUA	A,E,H	
2964	LIQUIDAMBAR TAIWANIANA	A,H	
2965	LIQUIDAMBER 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%.
2966	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%.
2967	LIQUORICE DRY	A,E,H	
2968	LIQUORICE LIQUID EXTRACT	A,E,H	
2969	LIQUORICE POWDER	A,E,H	
2970	LITCHI CHINENSIS	A,H	
2971	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
2972	LITHOSPERMUM OFFICINALE	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
2973	LITSEA CUBEBA	A,E,H	
2974	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%.
2975	LOBARIA PULMONARIA	A,H	
2976	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.
2977	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			administered by inhalation.
2978	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.
2979	LOLIUM PERENNE	A,H	
2980	LOLIUM TEMULENTUM	A,H	
2981	LONGIFOLENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total longifolene concentration in a medicine must be no more than 1%.
2982	LONICERA CAPRIFOLIUM	A,E,H	
2983	LONICERA JAPONICA	A,E,H	
2984	LONICERA PERICLYMENUM	A,H	
2985	LOPHATHERUM GRACILE	A,H	
2986	LOQUAT	E	
2987	LORANTHUS PARASITICUS	A,H	
2988	LOROPETALUM CHINENSIS	A,H	
2989	LOTUS CORNICULATUS	A,H	
2990	LOVAGE 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%.
2991	LOVAGE OIL	A,E,H	
2992	LOVAGE ROOT DRY	A,H	
2993	LOVAGE ROOT POWDER	A,H	
2994	LUDWIGIA PROSTRATA	A,H	
2995	LUFFA CYLINDRICA	A,H	
2996	LUFFA PURGANS	A,H	
2997	LUTEIN	A,E,H	Permitted for use as a colour for oral and topical use.
2998	LYCHEE	E	
2999	LYCIUM BARBARUM	A,H	
3000	LYCIUM CHINENSE	A,E,H	
3001	LYCOPENE	A,E	
3002	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.
3003	LYCOPODIUM ANNOTINUM	A,H	
3004	LYCOPODIUM CLAVATUM	A,H	
3005	LYCOPODIUM COMPLANATUM	A,H	
3006	LYCOPUS EUROPAEUS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3007	LYCOPUS LUCIDUS	A,H	
3008	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%.
3009	LYGODIUM JAPONICUM	A,H	
3010	LYSIMACHIA CHRISTINAE	A,H	
3011	LYSIMACHIA VULGARIS	A,H	
3012	LYSINE	A,E	
3013	LYSINE HYDROCHLORIDE	A,E	
3014	LYTHRUM HYSSOPIFOLIA	A,H	
3015	LYTHRUM SALICARIA	A,H	
3016	LYTHRUM VERTICILLATUM	A,H	
3017	MACADAMIA INTEGRIFOLIA	A,E	
3018	MACADAMIA NUT	E	
3019	MACADAMIA NUT OIL	E	
3020	MACADAMIA TERNIFOLIA	A,E,H	
3021	MACE	E,H	Only for use as an active homoeopathic ingredient. Safrole is a mandatory component of Mace.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			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%.
3022	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.
3023	MACROCYSTIS PYRIFERA	A,E,H	Iodine is a mandatory component of Macrocystis pyrifera. Only for external use when the concentration of available iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3024	MACROGOL 1000	E	
3025	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3026	MACROGOL 1500	E	
3027	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%.
3028	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3029	MACROGOL 20000	E	
3030	MACROGOL 300	E	
3031	MACROGOL 3000	E	
3032	MACROGOL 3350	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopeia.
3033	MACROGOL 40	E	Only for use in topical medicines for dermal application.
3034	MACROGOL 400	E	
3035	MACROGOL 4000	E	
3036	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3037	MACROGOL 600	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3038	MACROGOL 6000	E	
3039	MACROGOL 600000	E	
3040	MACROGOL 800	E	
3041	MACROGOL 8000	E	
3042	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%.
3043	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3044	MAGNESIUM AMINO ACID CHELATE	A,E,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. If used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium amino acid chelate. The quantity of magnesium in the medicine must be no more than 25%. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
3045	MAGNESIUM ASCORBATE	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.' The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3046	MAGNESIUM ASCORBATE MONOHYDRATE	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.' The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3047	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3048	MAGNESIUM ASPARTATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium aspartate tetrahydrate. The percentage of Magnesium from magnesium aspartate tetrahydrate should be calculated based on the molecular weight of magnesium aspartate tetrahydrate.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.-
3049	MAGNESIUM ASPARTATE DIHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium aspartate dihydrate. The percentage of magnesium from magnesium aspartate dihydrate should be calculated based on the molecular weight of magnesium aspartate dihydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3050	MAGNESIUM ASPARTATE TETRAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium aspartate tetrahydrate. The percentage of Magnesium from magnesium aspartate tetrahydrate should be calculated based on the molecular weight of magnesium aspartate tetrahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3051	MAGNESIUM CARBONATE HYDRATE	A,E,H	If used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of magnesium carbonate hydrate. The amount of magnesium in the active

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			ingredient should be calculated based on the molecular weight of magnesium carbonate hydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3052	MAGNESIUM CHLORIDE 4.5-HYDRATE	A	If used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of magnesium chloride 4.5-hydrate. The percentage of magnesium from magnesium chloride 4.5-hydrate should be calculated based on the molecular weight of magnesium chloride 4.5-hydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3053	MAGNESIUM CHLORIDE HEXAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium chloride hexahydrate. The percentage of magnesium from magnesium chloride hexahydrate should be calculated based on the molecular weight of magnesium chloride hexahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3054	MAGNESIUM CITRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium citrate. The percentage of magnesium from magnesium citrate should be calculated based on the molecular weight of magnesium citrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3055	MAGNESIUM CITRATE - DIBASIC TETRAHYDRATE	A	Only for use in oral medicines. When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium citrate - dibasic tetrahydrate. The percentage of Magnesium from Magnesium citrate - dibasic tetrahydrate should be calculated based on the molecular weight of Magnesium citrate - dibasic tetrahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3056	MAGNESIUM CITRATE NONAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium citrate nonahydrate. The percentage of magnesium from magnesium citrate nonahydrate should be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			calculated based on the molecular weight of magnesium citrate nonahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3057	MAGNESIUM CITRATE TETRADECAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium citrate tetradecahydrate. The percentage of magnesium from magnesium citrate tetradecahydrate should be calculated based on the molecular weight of magnesium citrate tetradecahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3058	MAGNESIUM DIGLUTAMATE	A,E,H	The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3059	MAGNESIUM GLUCONATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium gluconate. The percentage of magnesium from magnesium gluconate should be calculated based on the molecular weight of magnesium gluconate. The indication 'For mineral (may state the mineral) supplementation' is only

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			permitted when the medicine is for oral or sublingual use.
3060	MAGNESIUM GLYCEROPHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium glycerophosphate. The percentage of magnesium from magnesium glycerophosphate should be calculated based on the molecular weight of magnesium glycerophosphate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3061	MAGNESIUM GLYCINATE	A	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Magnesium is a mandatory component of Magnesium glycinate. The percentage of Magnesium from Magnesium glycinate should be calculated based on the molecular weight of Magnesium glycinate The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3062	MAGNESIUM GLYCINATE DIHYDRATE	A	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			supplementation. Magnesium is a mandatory component of Magnesium glycinate dihydrate. Based on molecular weights the declared quantity of Magnesium from Magnesium glycinate dihydrate must be no less than 11.1% and must be no more than 12.2% of th eMagnesium glycinate dihydrate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations.
3063	MAGNESIUM HYDROGEN PHOSPHATE	H	
3064	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 Pharmacopeia.
3065	MAGNESIUM LYSINATE	A	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Magnesium is a mandatory component of Magnesium lysinate. The percentage of Magnesium from Magnesium lysinate should be calculated based on the molecular weight of Magnesium lysinate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3066	MAGNESIUM METHIONINATE	A	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Magnesium is a mandatory component of magnesium methioninate. The percentage of magnesium from magnesium methioninate should be calculated based on the molecular weight of magnesium methioninate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3067	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3068	MAGNESIUM OROTATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium orotate . The percentage of magnesium from Magnesium orotate should be calculated based on the molecular weight of Magnesium orotate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3069	MAGNESIUM OROTATE DIHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			orotate dihydrate. The percentage of magnesium from magnesium orotate dihydrate should be calculated based on the molecular weight of magnesium orotate dihydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3070	MAGNESIUM OXIDE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium oxide. The percentage of Magnesium from Magnesium oxide should be calculated based on the molecular weight of Magnesium oxide. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3071	MAGNESIUM OXIDE - HEAVY	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium oxide - heavy. The percentage of Magnesium from Magnesium oxide – heavy should be calculated based on the molecular weight of Magnesium oxide – heavy. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			sublingual use.
3072	MAGNESIUM OXIDE - LIGHT	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium oxide - light. The percentage of Magnesium from Magnesium oxide - light should be calculated based on the molecular weight of Magnesium oxide - light. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3073	MAGNESIUM PHOSPHATE - DIBASIC TRIHYDRATE	A,E,H	Magnesium is a mandatory component of Magnesium phosphate - dibasic trihydrate. Based on molecular weights the accepted percentage of Magnesium from Magnesium phosphate - dibasic trihydrate is 13.9%. The declared quantity of Magnesium from Magnesium phosphate - dibasic trihydrate must be no less than 13.2% and must be no more than 14.6% of the Magnesium phosphate - dibasic trihydrate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations.
3074	MAGNESIUM PHOSPHATE PENTAHYDRATE	A,E,H	If used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of magnesium phosphate pentahydrate. The amount of magnesium in the active ingredient should be calculated based on the molecular weight of magnesium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			phosphate pentahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3075	MAGNESIUM PHOSPHATE TRIBASIC	A,E,H	Magnesium is a mandatory component of magnesium phosphate tribasic. Based on molecular weights the accepted percentage of Magnesium from magnesium phosphate tribasic is 27.7%. The declared quantity of Magnesium from magnesium phosphate tribasic must be no less than 26.3% and must be no more than 29.1% of the magnesium phosphate tribasic in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations.
3076	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams. When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium pyruvate. The percentage of magnesium from magnesium pyruvate should be calculated based on the molecular weight of pyruvate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3077	MAGNESIUM STEARATE	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3078	MAGNESIUM SULFATE - DRIED	A,E,H	When used internally, the maximum recommended daily dose must be no more than 1.5g. When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium sulfate - dried. The percentage of Magnesium from Magnesium sulfate - dried should be calculated based on the molecular weight of Magnesium sulfate - dried. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3079	MAGNESIUM SULFATE DIHYDRATE	A,E,H	When used internally, the maximum recommended daily dose must be no more than 1.5g. When used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium sulfate dihydrate. The percentage of Magnesium from Magnesium sulfate dihydrate should be calculated based on the molecular weight of Magnesium sulfate dihydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3080	MAGNESIUM SULFATE HEPTAHYDRATE	A,E,H	When used internally, the maximum recommended daily dose must be no more

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			than 1.5g. When used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of magnesium sulfate heptahydrate. The percentage of Magnesium from magnesium sulfate heptahydrate should be calculated based on the molecular weight of magnesium sulfate heptahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3081	MAGNESIUM SULFATE MONOHYDRATE	A,E,H	When used internally, the maximum recommended daily dose must be no more than 1.5g. When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium sulfate monohydrate. The percentage of Magnesium from Magnesium sulfate monohydrate should be calculated based on the molecular weight of Magnesium sulfate monohydrate. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
3082	MAGNESIUM SULFATE TRIHYDRATE	A,E,H	When used internally, the maximum recommended daily dose must be no more than 1.5g. When used as an active ingredient and the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium sulfate trihydrate. The percentage of Magnesium from Magnesium sulfate trihydrate should be calculated based on the molecular weight of Magnesium sulfate trihydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3083	MAGNESIUM TRISILICATE	E	
3084	MAGNOLIA GLAUCA	A,H	
3085	MAGNOLIA LILIFLORA	A,H	
3086	MAGNOLIA OBOVATA	A,H	
3087	MAGNOLIA OFFICINALIS	A,E,H	
3088	MAGNOLIA SALICIFOLIA	A,H	
3089	MAIZE	E	
3090	MAIZE BRAN	E	
3091	MAIZE OIL	A,E,H	
3092	MAIZE SYRUP - HIGH FRUCTOSE	E	Permitted for use only in combination 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3093	MALACHITE GREEN	E	Permitted for use as a colour for topical use.
3094	MALIC ACID	E	Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose.
3095	MALPIGHIA GLABRA	A,E,H	
3096	MALT EXTRACT	E	
3097	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]’.
3098	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).
3099	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. When the route of administration is other than topical or mucosal, the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3100	MALTOL	E	
3101	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%.
3102	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: - (LACT) 'Contains lactose' (or words to that effect).
3103	MALUS DOMESTICA	A,E,H	The concentration of amygdalin in the medicine must be no more than 0%.
3104	MALUS PUMILA	A,E,H	
3105	MALUS SYLVESTRIS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3106	MALVA MOSCHATA	A,H	
3107	MALVA SYLVESTRIS	A,E,H	
3108	MALVA VERTICILLATA	A,H	
3109	MANDARIN	E	
3110	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%.
3111	MANDARIN OIL COLDPRESSED	A,E,H	When used internally, oxedrine is a mandatory component of mandarin oil coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3112	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%.
3113	MANDARIN RESIDUE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
3114	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%.
3115	MANDRAGORA OFFICINARUM	A,H	Atropine, hyoscine and hyoscyamine are mandatory components of Mandragora officinarum. The concentration in the medicine must be no more than 10 mg/kg or 10 mL/L or 0.001%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%. The concentration of hyoscine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%. The concentration of hyoscyamine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
3116	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3117	MANGANESE (II) DIASPARTATE	A,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Manganese is a mandatory component of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Manganese (II) diaspartate. The percentage of Manganese from Manganese (II) diaspartate should be calculated based on the molecular weight of Manganese (II) diaspartate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3118	MANGANESE (II) GLYCINATE	A,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Manganese is a mandatory component of Manganese (II) glycinate. The percentage of Manganese from Manganese (II) glycinate should be calculated based on the molecular weight of Manganese (II) glycinate. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
3119	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3120	MANGANESE AMINO ACID CHELATE	A,E,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. If used as an active ingredient and the medicine is intended as a mineral supplementation, the equivalent quantity

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			of Manganese. The declared quantity of Manganese must be no more than 25% of the Manganese amino acid chelate in the formulation. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3121	MANGANESE CHLORIDE TETRAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, manganese is a mandatory component of manganese chloride tetrahydrate. The percentage of manganese from manganese chloride tetrahydrate should be calculated based on the molecular weight of manganese chloride tetrahydrate. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
3122	MANGANESE DIASPARTATE	A,E,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. If used as an active ingredient and the medicine is intended as a mineral supplementation, the equivalent quantity of Manganese is required. The declared quantity of Manganese must be no more than 25% of the manganese diaspartate in the formulation. The indication 'For mineral (may state the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3123	MANGANESE GLUCONATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, Manganese is a mandatory component of Manganese gluconate. The percentage of Manganese from Manganese gluconate should be calculated based on the molecular weight of Manganese gluconate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3124	MANGANESE GLYCEROPHOSPHATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, Manganese is a mandatory component of Manganese glycerophosphate. The percentage of Manganese from Manganese glycerophosphate should be calculated based on the molecular weight of Manganese glycerophosphate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3125	MANGANESE OXIDE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, Manganese is a mandatory component of Manganese oxide. The percentage of Manganese from

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Manganese oxide should be calculated based on the molecular weight of Manganese oxide. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3126	MANGANESE SULFATE MONOHYDRATE	A,E,H	If used as an active ingredient and the medicine is intended as a mineral supplementation, manganese is a mandatory component of Manganese sulfate monohydrate. The percentage of manganese from Manganese sulfate monohydrate should be calculated based on the molecular weight of Manganese sulfate monohydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3127	MANGANESE SULFATE TETRAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, manganese is a mandatory component of manganese sulfate tetrahydrate. The percentage of manganese from manganese sulfate tetrahydrate should be calculated based on the molecular weight of manganese sulfate tetrahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3128	MANGIFERA INDICA	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3129	MANGO	E,H	
3130	MANIHOT UTILISSIMA	A,H	
3131	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).
3132	MARANTA ARUNDINACEA	A,H	
3133	MARJORAM OIL SPANISH	A,E,H	When the concentration in the preparation is more than 50%, the nominal capacity of the container must be no more than 50 mL, the medicine must have a restricted flow insert fitted to the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3134	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).
3135	MARRUBIUM VULGARE	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3136	MARSDENIA CUNDURANGO	A,H	
3137	MARSHMALLOW ROOT DRY	A,H	
3138	MARSHMALLOW ROOT POWDER	A,H	
3139	MARTYNIA PARVIFLORA	A,H	
3140	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%.
3141	MASTIC	A,H	
3142	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%.
3143	MATRICARIA CHAMOMILLA	A,E,H	
3144	MATRICARIA FLOWER DRY	A,E,H	
3145	MATRICARIA RECUTITA	A,E,H	
3146	MEADOWSWEET HERB DRY	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3147	MEADOWSWEET HERB POWDER	A,H	
3148	MECOBALAMIN (CO-METHYLCOBALAMIN)	A	Only for use in oral medicines.
3149	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.
3150	MEDIUM CHAIN TRIGLYCERIDES	E	
3151	MELALEUCA ALTERNIFOLIA	A,E,H	Melaleuca oil, cajuput oil and cineole are mandatory components of Melaleuca alternifolia. When the plant preparation is oil and the concentration of Melaleuca oil, cajuput oil or cineole in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or word to that effect) - (NTAKEN) ‘Not to be taken’. When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container. Where the nominal capacity of the container is more than 15 mL but less than or equal to 25 mL, then a child resistant closure and restricted flow insert must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fitted on the container.
3152	MELALEUCA CAJUPUTI	A,E,H	Cineole, melaleuca oil and cajuput oil are a mandatory components of Melaleuca cajuputi. When the plant preparation is oil and the concentration of Cineole, melaleuca oil or cajuput oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container. Where the nominal capacity of the container is more than 15 mL but less than or equal to 25 mL, then a child resistant closure and restricted flow insert must be fitted on the container.
3153	MELALEUCA DISSITIFLORA	A,H	Cineole, melaleuca oil and cajuput oil are a mandatory components of Melaleuca dissitiflora. When the plant preparation is oil and the concentration of Cineole, melaleuca oil or cajuput oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			(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.
3154	MELALEUCA ERICIFOLIA	A,E,H	Cineole, melaleuca oil and cajuput oil are mandatory components of Melaleuca ericifolia. When the plant preparation is oil and the concentration of Cineole, melaleuca oil or cajuput oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container. Where the nominal capacity of the container is more than 15 mL but less than or equal to 25 mL, then a child resistant closure and restricted flow insert must be fitted on the container.
3155	MELALEUCA	A,H	Cineole, melaleuca oil and cajuput oil are mandatory components of Melaleuca

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	LINARIIFOLIA		linariifolia. When the plant preparation is oil and the concentration of Cineole, melaleuca oil or cajuput oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container. Where the nominal capacity of the container is more than 15 mL but less than or equal to 25 mL, then a child resistant closure and restricted flow insert must be fitted on the container.
3156	MELALEUCA OIL	A,E,H	Cineole and cajuput oil are a mandatory components of Melaleuca Oil. When the plant preparation is oil and the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. When the nominal capacity of the container is 15 mL or less, then a restricted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			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.
3157	MELALEUCA QUINQUENERVIA	A,E,H	Cineole, melaleuca oil and cajuput oil are a mandatory components of Melaleuca quinquenervia. When the plant preparation is oil and the concentration of Cineole, melaleuca oil or cajuput oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or word to that effect) - (NTAKEN) ‘Not to be taken’. When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container. Where the nominal capacity of the container is more than 15 mL but less than or equal to 25 mL, then a child resistant closure and restricted flow insert must be fitted on the container.
3158	MELICOPE PTELEIFOLIA	A,H	
3159	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3160	MELISSA OFFICINALIS	A,E,H	
3161	MELON	E	
3162	MENADIONE SODIUM BISULFITE	E	
3163	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.
3164	MENISPERMUM CANADENSE	A,H	
3165	MENTHA AQUATICA	A,H	
3166	MENTHA ARVENSIS	A,E,H	
3167	MENTHA ARVENSIS LEAF 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 than 1%.
3168	MENTHA ARVENSIS OIL	E	Permitted for use only in combination 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3169	MENTHA HAPLOCALYX	A,E,H	
3170	MENTHA PULEGIUM	A,H	D-Pulegone and volatile oil components (of Mentha pulegium) are mandatory components of Mentha pulegium. When the nominal capacity of the container is more than 15 mL, 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 mL 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, the maximum recommended daily dose must be no more than 150 mg of Mentha pulegium oil. When the medicine is for a use other than topical, the maximum recommended daily dose must be no more than 50 mg of Mentha pulegium oil.
3171	MENTHA SPICATA	A,E,H	
3172	MENTHA X CARDIACA	A,E,H	
3173	MENTHA X PIPERITA	A,E,H	
3174	MENTHA X PIPERITA NOTHOSUBSP. CITRATA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3175	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%.
3176	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%.
3177	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%.
3178	MENTHOL	A,E	When used as an active ingredient, permitted only in medicated space sprays and medicated lozenges.
3179	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%.
3180	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3181	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%.
3182	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3183	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%.
3184	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%.
3185	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 be no more than 5%.
3186	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%.
3187	MENTHYL LACTATE	E	
3188	MENYANTHES	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	TRIFOLIATA		
3189	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient.
3190	MERCURIC IODIDE - RED	H	Only for use as an active homoeopathic ingredient.
3191	MERCURY	H	Only for use as an active homoeopathic ingredient.
3192	MERCURY - HAHNEMANN'S SOLUBLE	H	Only for use as an active homoeopathic ingredient.
3193	MESPILUS GERMANICA	A,H	
3194	METACRESOL	E	Only for use in topical medicines for dermal application.
3195	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3196	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%.
3197	METHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
3198	METHIONINE	A,E	
3199	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%.
3200	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%.
3201	METHYL-PARA-TERT-BUTYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3202	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%.
3203	METHYL 2-OCTYNOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3204	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 1%.
3205	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%.
3206	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%.
3207	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3208	METHYL ANISATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3209	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3210	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3211	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%.
3212	METHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3213	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%.
3214	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%.
3215	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3216	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%.
3217	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%.
3218	METHYL CYCLOPENTENOLONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3219	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%.
3220	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 1%.
3221	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%.
3222	METHYL DIISOPROPYL PROPIONAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3223	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3224	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%.
3225	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%.
3226	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3227	METHYL GLUCETH-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. Residue levels of ethylene oxide are to be kept below the level of detection.
3228	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.
3229	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%.
3230	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3231	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3232	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3233	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3234	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3235	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%.
3236	METHYL HEXYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3237	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%.
3238	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3239	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3240	METHYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) ‘Contains hydroxybenzoates’

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			(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) if product contains one hydroxybenzoate source.
3241	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%.
3242	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%.
3243	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%.
3244	METHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%.
3245	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%.
3246	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%.
3247	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%.
3248	METHYL LINOLENATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3249	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%.
3250	METHYL METHACRYLATE	E	
3251	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 1%.
3252	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%.
3253	METHYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3254	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%.
3255	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%.
3256	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3257	METHYL OCTIN CARBONATE	E	
3258	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%.
3259	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%.
3260	METHYL PHENYL CARBINYL-ISO-BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3261	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%.
3262	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more 1%.
3263	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%.
3264	METHYL ROSINATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3265	METHYL SALICYLATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.001%. For topical use, when the concentration in a liquid preparation is more than 5%, and the dosage form is other than spray, the medicine requires child resistant packaging. For topical use, when the concentration in a liquid preparation is more than 5%, and the dosage form is spray, the medicine does not require child resistant packaging but the delivery device must be 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dosage unit, and actuation of the spay device is ergonomically difficult for young children to accomplish.
3266	METHYL STEARATE	E	
3267	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%.
3268	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%.
3269	METHYLATED SPIRIT - INDUSTRIAL	E	
3270	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%.
3271	METHYLCELLULOSE	A,E	
3272	METHYLCHLOROISOTHIAZOLINONE	E	Only for use in topical medicines for dermal application.
3273	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%.
3274	METHYLDIBROMO	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	GLUTARONITRILE		dermal application.
3275	METHYLENE BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYLPHENOL	A	Only for use as an active ingredient in sunscreens. 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%.
3276	METHYLISOTHIAZOLINONE	E	Only for use in topical medicines for dermal application.
3277	METHYLMERCAPTAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3278	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%.
3279	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%.
3280	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3281	MICA	E	Only for use when the route of administration is oral, dental or topical. The concentration in oral medicines must

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			be no more than 2.5%. The concentration in dental toothpastes must be no more than 0.5%.
3282	MICROCALICIUM ARENARIUM	A,H	
3283	MICROCOCCUS LUTEUS LYSATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
3284	MICROCOS PANICULATA	A,H	
3285	MICROSPORUM GYPSEUM	A,H	
3286	MILK - GOAT	E	
3287	MILK - NONFAT DRY	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).
3288	MILK - WHOLE DRY	E	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).
3289	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%.
3290	MILK THISTLE FRUIT DRY	A,H	
3291	MILK THISTLE FRUIT POWDER	A,H	
3292	MILLET	E	
3293	MILLETTIA DIELSIANA	A,H	
3294	MIMOSA ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3295	MIMULUS GUTTATUS	A,H	
3296	MINT OIL DEMENTHOLISED	A,E,H	
3297	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%.
3298	MITCHELLA REPENS	A,H	
3299	MIXED TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3300	MOLASSES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
3301	MOLASSES - BLACKSTRAP	E	When for oral or sublingual use, Sucrose is a mandatory component of Molasses - blackstrap. 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).
3302	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.
3303	MOLYBDENUM	A	Molybdenum is a mandatory component of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	TRIOXIDE		Molybdenum trioxide. The maximum daily dose of molybdenum from molybdenum trioxide must be no more than 125 micrograms. Based on molecular weights the accepted percentage of Molybdenum from Molybdenum trioxide is 66.65%. The declared quantity of Molybdenum from Molybdenum trioxide must be no less than 63.3% and must be no more than 70% of the Molybdenum trioxide in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations.
3304	MOMORDICA BALSAMINA	A,H	
3305	MOMORDICA CHARANTIA	A,H	
3306	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.
3307	MONARDA DIDYMA	A,H	
3308	MONO- AND DI-GLYCERIDES	E	
3309	MONOBASIC SODIUM PHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, sodium is a mandatory component of monobasic sodium phosphate. The percentage of sodium from monobasic sodium phosphate should be calculated based on the molecular weight of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			monobasic sodium phosphate. 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). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3310	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3311	MONOPHOSPHOTHIAMINE	A	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			should not replace a balanced diet.'
3312	MONOPHOSPHOTHIAMINE DIHYDRATE	A	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3313	MONOPOTASSIUM GLUTAMATE	A,E	
3314	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).'
3315	MONOSODIUM GLUTAMATE MONOHYDRATE	A,E	
3316	MONSTERA DELICIOSA	A,H	
3317	MONTAN WAX	E	
3318	MORDANT RED 11	E	Permitted for use as a colour for topical use. The concentration in the medicine must be no more than 0.05%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3319	MORINDA CITRIFOLIA	A,H	Only for use when the plant part is fruit and the plant preparation is fruit juice or fruit powder. Fruit powder must be produced by freeze drying the whole fruit (excluding the seeds).
3320	MORINDA OFFICINALIS	A,H	
3321	MORINGA OLEIFERA	A,H	
3322	MORUS ALBA	A,H	
3323	MORUS BOMBYCIS	A,H	
3324	MORUS NIGRA	A,E,H	
3325	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%.
3326	MOTHERWORT HERB DRY	A,H	
3327	MOTHERWORT HERB POWDER	A,H	
3328	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%.
3329	MULBERRY	E	
3330	MUNG BEAN	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3331	MURRAYA KOENIGII	A,H	
3332	MURRAYA PANICULATA	A,H	
3333	MUSA X PARADISIACA	A,H	
3334	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3335	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%.
3336	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3337	MUSKS	H	Only for use as an active homoeopathic ingredient.
3338	MUSTARD	E	Allyl isothiocyanate is a mandatory component of Mustard. The maximum daily dose must not provide more than 20 mg of allyl isothiocyanate.
3339	MUSTARD OIL	E	Allyl isothiocyanate is a mandatory component of Mustard oil. The maximum daily dose must not provide more than 20 mg of allyl isothiocyanate.
3340	MUSTARD SEED OIL	E	Allyl isothiocyanate is a mandatory component of Mustard seed oil. The maximum daily dose must not provide more than 20 mg of allyl isothiocyanate.
3341	MYOSOTIS ARVENSIS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3342	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%.
3343	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%.
3344	MYRICA CERIFERA	A,E,H	
3345	MYRISTIC ACID	E	
3346	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%.
3347	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 1%. When the plant preparation is oil and the concentration 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 word to that effect).
3348	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3349	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3350	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3351	MYROXYLON BALSAMUM	A,E,H	
3352	MYROXYLON BALSAMUM VAR. PEREIRAE	A,H	
3353	MYRRH	A,H	
3354	MYRRH OIL	A,E,H	
3355	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more 1%.
3356	MYRRHIS ODORATA	A,H	
3357	MYRSINE AFRICANA	A,H	
3358	MYRTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3359	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%.
3360	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%.
3361	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%.
3362	MYRTUS COMMUNIS	A,E,H	
3363	N-BUTYL SULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3364	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%.
3365	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%.
3366	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3367	NARDOSTACHYS CHINENSIS	A,H	
3368	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%.
3369	NASTURTIUM OFFICINALE	A,E,H	
3370	NATURAL CHERRY FLAVOUR	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%.
3371	NAUCLEA OFFICINALIS	A,H	
3372	NELUMBO NUCIFERA	A,H	
3373	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%.
3374	NEOHESPERIDIN-DIHYDROCHALCONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%
3375	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%.
3376	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%.
3377	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3378	NEOPENTYL GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3379	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3380	NEOPICRORHIZA SCROPHULARIIFLORA	A,H	
3381	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%.
3382	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%.
3383	NERIUM OLEANDER	A,H	The concentration of equivalent dry Nerium oleander in the product must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3384	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3385	NEROLIDOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3386	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%.
3387	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%.
3388	NICKEL	H	Only for use as an active homoeopathic ingredient.
3389	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3390	NICOTINAMIDE	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3391	NICOTINAMIDE ASCORBATE	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3392	NICOTINIC ACID	A,E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3393	NIGELLA DAMASCENA	A,H	
3394	NIGELLA SATIVA	A,E,H	
3395	NIGRITELLA ANGUSTIFOLIA	A,H	
3396	NITRIC ACID	E,H	Only for use as an active homoeopathic ingredient. The concentration of nitric acid in the medicine must be no more than 0.5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3397	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%.
3398	NONANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3399	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%.
3400	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3401	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3402	NONOXINOL 12	E	For use in hand scrub formulations for healthcare professionals only. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3403	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%.
3404	NONOXINOL 9	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
3405	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%.
3406	NOOTKATONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3407	NOPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 1%.
3408	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%.
3409	NOTOPTERYGIUM FORBESII	A,H	
3410	NOTOPTERYGIUM INCISIUM	A,H	
3411	NUPHAR JAPONICA	A,H	
3412	NUPHAR LUTEA	A,H	
3413	NUTMEG DRY	A,E,H	Safrole is a mandatory component of Nutmeg Dry. When for internal use then the concentration of safrole from all ingredients in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole from all ingredients in the medicine must be no more than 1%.
3414	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			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).
3415	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%.
3416	NUX VOMICA DRY	A,H	Strychnine (of Strychnos spp.) is a mandatory component of Nux Vomica Dry. The concentration of in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3417	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%.
3418	NYCTANTHES ARBOR-	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	TRISTIS		
3419	NYLON	E	Only for use in topical medicines for dermal application.
3420	NYLON-12	E	Only for use in topical medicines for dermal application.
3421	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3422	NYMPHAEA ALBA	A,E,H	
3423	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.
3424	NYMPHAEA ODORATA	A,H	
3425	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%.
3426	OAKMOSS	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%.
3427	OAKMOSS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3428	OAT	E,H	Only for use as a homoeopathic ingredient. Gluten is a mandatory component of Oat when the route of administration is other than topical and mucosal. When the route of administration is other than topical or muscosal, the medicine requires the warning statement: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3429	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3430	OATMEAL COLLOIDAL	A,E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3431	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%.
3432	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%.
3433	OCIMUM BASILICUM	A,E,H	When the plant part is oil, Methyl chavicol is a mandatory component of Ocimum basilicum. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and requires the following warning statement on the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3434	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 other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (NTAKEN) 'Not to be taken'. In essential oil 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 have a restricted flow insert and child resistant closure 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'. When the plant preparation is oil, Methyl chavicol is a mandatory component of Ocimum kilimandscharicum. When the concentration of Methyl chavicol in a 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 the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3435	OCIMUM MINIMUM	A,H	When the plant part is oil, Methyl chavicol is a mandatory component of Ocimum minimum. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL. When the concentration of Methyl chavicol in the medicine is more than 5%

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3436	OCIMUM TENUIFLORUM	A,H	When the plant part is oil, Methyl chavicol is a mandatory component of Ocimum tenuiflorum. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3437	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%.
3438	OCTACOSANOL	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3439	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%.
3440	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3441	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%.
3442	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%.
3443	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%.
3444	OCTANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3445	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%.
3446	OCTANOIC ACID	A	Only for use in oral and topical medicines. When for topical use, the concentration in the medicine must be no more than 2% (w/w).
3447	OCTHILINONE	E	Only for use in topical medicines for dermal application.
3448	OCTOCRYLENE	A	Only for use as an active ingredient in sunscreens. 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%.
3449	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3450	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3451	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3452	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%.
3453	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3454	OCTYL METHOXYCINNAMATE	A	Only for use as an active ingredient in sunscreens. 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%.
3455	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3456	OCTYL SALICYLATE	A	Only for use as an active ingredient in sunscreens. 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3457	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.
3458	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).
3459	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3460	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.
3461	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%.
3462	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
3463	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 2%.
3464	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%.
3465	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.
3466	OENANTHE CROCATA	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3467	OENOTHERA BIENNIS	A,E,H	
3468	OENOTHERA STRICTA	A,H	
3469	OKOUBAKA AUBREVILLEI	A,H	
3470	OLDENLANDIA DIFFUSA	A,E,H	
3471	OLEA EUROPAEA	A,E,H	
3472	OLEIC ACID	E	
3473	OLETH-10	E	Only for use in topical medicines for dermal application.
3474	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			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%.
3475	OLETH-20	E	Only for use in topical medicines for dermal application.
3476	OLETH-3	E	Only for use in topical medicines for dermal application.
3477	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%.
3478	OLETH-5	E	Only for use in topical medicines for dermal application.
3479	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3480	OLIBANUM OIL	A,E,H	
3481	OLIGOFRUCTOSE	A,E	
3482	OLIVE	E	
3483	OLIVE OIL	A,E,H	
3484	OMEGA-3-ACID ETHYL ESTERS 90	A	Only for use in oral medicines. The maximum recommended daily dose must not provide more than 2750 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:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			-'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).
3485	OMEGA-3 FISH OIL PHYTOSTEROL ESTERS	A	The medicine requires the following warning statements on the medicine label: - (VOPE) 'There is no benefit from taking more than 3g/day of phytosterols from all sources' - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
3486	ONION	E	
3487	ONION OIL	A,H	
3488	ONONIS SPINOSA	A,E,H	
3489	ONOPORDON ACANTHIUM	A,H	
3490	ONOSMODIUM VIRGINIANUM	A,H	
3491	OPHIOPOGON JAPONICUS	A,H	
3492	OPOPANAX CHIRONIUM	A,H	
3493	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more 1%.
3494	OPUNTIA FICUS-INDICA	A,H	
3495	ORANGE	E	
3496	ORANGE FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3497	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.
3498	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%.
3499	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more 1%.
3500	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.
3501	ORANGE OIL BITTER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3502	ORANGE OIL BITTER COLDPRESSED	A,E,H	When used internally, oxedrine is a mandatory component of orange oil bitter coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 1.4% or less of orange oil bitter coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3503	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%.
3504	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.
3505	ORANGE OIL SWEET	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3506	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.
3507	ORANGE PEEL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3508	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.
3509	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%.
3510	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3511	OREODAPHNE CALIFORNICA	A,H	
3512	ORIGANUM MAJORANA	A,H	
3513	ORIGANUM OIL	E	Permitted for use only in combination with other ingredients as a fragrance. If used as a fragrance the total concentration in the medicine must be no more than 1%.
3514	ORIGANUM OIL SPANISH	A,E,H	
3515	ORIGANUM VULGARE	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3516	ORNITHINE	A,E	
3517	ORNITHINE ASPARTATE	A,E	
3518	ORNITHINE MONOHYDROCHLORIDE	A,E	
3519	ORNITHOGALUM UMBELLATUM	A,H	
3520	OROSTACHYS FIMBRIATA	A,H	
3521	OROXYLUM INDICUM	A,H	
3522	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%.
3523	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%.
3524	ORRIS ROOT EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3525	ORRIS ROOT OIL	A,E,H	
3526	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%.
3527	ORTHO-CYMEN-5-OL	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 0.1%.
3528	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%.
3529	ORTHOSIPHON ARISTATUS	A,H	
3530	ORYZA SATIVA	A,E,H	
3531	ORYZANOL	E	
3532	OSBECKIA CHINENSIS	A,H	
3533	OSMANTHUS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3534	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%.
3535	OTTELIA ALISMOIDES	A,H	
3536	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%.
3537	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3538	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%.
3539	OXALIC ACID	H	Only for use as an active homoeopathic ingredient.
3540	OXALIS ACETOSELLA	A,H	
3541	OXYBENZONE	A	Only for use as an active ingredient in sunscreens. 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%.
3542	OYSTER	E	
3543	OYSTER SHELL	A,E,H	