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** |
| --- | --- | --- | --- |
| 2800 | KADSURA COCCINEA | A,H |  |
| 2801 | KAEMPFERIA GALANGA | A,H |  |
| 2802 | KALMIA LATIFOLIA | A,H |  |
| 2803 | KAOLIN | E |  |
| 2804 | KELP DRY | A,H | Iodine is a mandatory component of Kelp dry.Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use. |
| 2805 | KELP POWDER | A,E,H | Iodine is a mandatory component of Kelp powder.Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.  |
| 2806 | 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%. |
| 2807 | 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%.  |
| 2808 | KIDNEY BEAN | E |  |
| 2809 | 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%.  |
| 2810 | KIWI FRUIT | E |  |
| 2811 | KNAUTIA ARVENSIS | A,H |  |
| 2812 | KOREAN GINSENG ROOT DRY | A,H |  |
| 2813 | KOREAN GINSENG ROOT POWDER | A,H |  |
| 2814 | KRAMERIA IXIENA | A,H |  |
| 2815 | KRAMERIA LAPPACEA | A,H |  |
| 2816 | 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'. |
| 2817 | 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%. |
| 2818 | 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%. |
| 2819 | 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%. |
| 2820 | 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%. |
| 2821 | L-LINALOOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 2822 | 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%. |
| 2823 | 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%. |
| 2824 | 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%. |
| 2825 | LABDANUM ABSOLUTE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2826 | 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%. |
| 2827 | LABDANUM OIL | A,E,H |  |
| 2828 | 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%. |
| 2829 | LACTALBUMIN | E |  |
| 2830 | LACTIC ACID | A,E,H | When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time.Sponsors should consider the impact of excipients containing alpha hydroxy acids on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose. |
| 2831 | 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 that effect)- (COWMK) 'Derived from cows milk'. |
| 2832 | LACTOBACILLUS ACIDOPHILUS | A |  |
| 2833 | LACTOBACILLUS AMYLOVORUS | A |  |
| 2834 | LACTOBACILLUS BREVIS | A |  |
| 2835 | LACTOBACILLUS CASEI | A |  |
| 2836 | LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI | A |  |
| 2837 | LACTOBACILLUS CRISPATUS | A |  |
| 2838 | LACTOBACILLUS DELBRUECKII SSP BULGARICUS | A |  |
| 2839 | LACTOBACILLUS DELBRUECKII SSP LACTIS | A |  |
| 2840 | LACTOBACILLUS FERMENTUM | A |  |
| 2841 | LACTOBACILLUS GALLINARUM | A |  |
| 2842 | LACTOBACILLUS GASSERI | A |  |
| 2843 | LACTOBACILLUS HELVETICUS | A |  |
| 2844 | LACTOBACILLUS JOHNSONII | A |  |
| 2845 | LACTOBACILLUS KEFIRANOFACIENS | A |  |
| 2846 | LACTOBACILLUS KEFIRGRANUM | A |  |
| 2847 | LACTOBACILLUS KEFIRI | A |  |
| 2848 | LACTOBACILLUS PARACASEI | A |  |
| 2849 | LACTOBACILLUS PARACASEI SUBSP. PARACASEI | A |  |
| 2850 | LACTOBACILLUS PLANTARUM | A |  |
| 2851 | LACTOBACILLUS REUTERI | A |  |
| 2852 | LACTOBACILLUS RHAMNOSUS | A |  |
| 2853 | LACTOBACILLUS SALIVARIUS SSP SALICINIUS | A |  |
| 2854 | LACTOBACILLUS SALIVARIUS SSP SALIVARIUS | A |  |
| 2855 | LACTOBIONIC ACID | E | Only for use in topical medicines for dermal application. |
| 2856 | LACTOSCATONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2857 | 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]’. |
| 2858 | LACTOSE MONOHYDRATE | E | When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose monohydrate, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:- (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars [or words to that effect]’ if medicine contains two or more sugars. If one of the sugars is lactose monohydrate then the medicine also requires the following warning statement on the medicine label:- (LACT) ‘Contains lactose monohydrate [or words to that effect]’. |
| 2859 | LACTUCA SATIVA | A,H |  |
| 2860 | LACTUCA VIROSA | A,H |  |
| 2861 | LACTULOSE | E |  |
| 2862 | LACTULOSE SOLUTION | A | When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time. |
| 2863 | LAGENARIA VULGARIS | A,H |  |
| 2864 | LAMINARIA CLOUSTONI | A,E,H | Iodine is a mandatory component of Laminaria cloustoni.Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use. |
| 2865 | LAMINARIA DIGITATA | A,E,H | Iodine is a mandatory component of Laminaria digitata and must be declared in the application.Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use. |
| 2866 | LAMINARIA JAPONICA | A,E,H | Iodine is a mandatory component of Laminaria japonica.Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use. |
| 2867 | LAMIUM ALBUM | A,H |  |
| 2868 | LANETH-5 | E | Only for use in topical medicines for dermal application. |
| 2869 | LANOLIN ALCOHOL | E | Only for use in topical medicines for dermal application. |
| 2870 | LANOLIN OIL | E | Only for use in topical medicines for dermal application. |
| 2871 | LANOLIN WAX | E | Only for use in topical medicines for dermal application. |
| 2872 | LANTANA CAMARA | A,H | The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara. |
| 2873 | LARIX ARABINOGALACTAN | A,E | Only for use in oral medicines.The ingredient must be derived from Larix occidentalis or Larix larcinia.The maximum recommended daily dose must be no more than 15 grams.The concentration of polysaccharides in the medicine must be equal to or more than 85%. |
| 2874 | LARIX DECIDUA | A,H |  |
| 2875 | 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.  |
| 2876 | 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'.  |
| 2877 | 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. |
| 2878 | LAURAMINE OXIDE | E |  |
| 2879 | LAUREL LEAF OIL | A,H |  |
| 2880 | LAURETH-10 | E | Only for use in topical medicines for dermal application. |
| 2881 | LAURETH-12 | E | Only for use in topical medicines for dermal application. |
| 2882 | 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. |
| 2883 | LAURETH-23 | E | Only for use in topical medicines for dermal application. |
| 2884 | LAURETH-3 | E | Only for use in topical medicines for dermal application. |
| 2885 | LAURETH-4 | E | Only for use in topical medicines for dermal application. |
| 2886 | LAURETH-7 | E | Only for use in topical medicines for dermal application. |
| 2887 | LAURETH-8 | E |  |
| 2888 | 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. |
| 2889 | 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%. |
| 2890 | LAUROMACROGOL 400 | E | Only for use in topical medicines for dermal application. |
| 2891 | LAUROYL LYSINE | 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 0.75%. |
| 2892 | LAURUS NOBILIS | A,E,H | When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is less than or equal to 15 millilitres, a restricted flow insert must be fitted on the container.When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is greater than 15 millilitres, a child resistant closure must be fitted on the container. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25%, the medicine must include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'. |
| 2893 | 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%. |
| 2894 | LAURYL BETAINE | E | Only for use in topical medicines for dermal application. |
| 2895 | 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%. |
| 2896 | 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. |
| 2897 | 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%. |
| 2898 | 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%. |
| 2899 | 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%. |
| 2900 | 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. |
| 2901 | 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. |
| 2902 | LAURYL PYRROLIDONE | E | Only for use in topical medicines for dermal application. |
| 2903 | LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN | E | Only for use in topical medicines for dermal application. |
| 2904 | 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%. |
| 2905 | LAURYLMETICONE COPOLYOL | E | Only for use in topical medicines for dermal application. |
| 2906 | 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%. |
| 2907 | LAVANDIN OIL ABRIAL | A,E,H |  |
| 2908 | 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%. |
| 2909 | 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, the nominal capacity of the container must be no more than 25 millilitres.In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must also have a child resistant closure fitted on the container. |
| 2910 | LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA | A,E,H | Camphor is a mandatory component of Lavandula angustifolia subsp. angustifolia.In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres.In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must also have a child resistant closure fitted on the container. |
| 2911 | 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 oil or distillates, the concentration of camphor must be no more than 2.5%.. |
| 2912 | 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‑ (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'. |
| 2913 | LAWSONIA INERMIS | A,H |  |
| 2914 | LEAD | H | Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.  |
| 2915 | LEAD ACETATE | H |  Only for use as an active homoeopathic ingredient. |
| 2916 | LEAF ACETAL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2917 | LECITHIN | A,E |  |
| 2918 | LEDEBOURIELLA SESELOIDES | A,H |  |
| 2919 | LEDUM GROENLANDICUM | A,H |  |
| 2920 | 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 Ledum palustre. |
| 2921 | LEMNA MINOR | A,H |  |
| 2922 | 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. |
| 2923 | LEMON BALM LEAF DRY | A,H |  |
| 2924 | LEMON BALM LEAF POWDER | A,E,H |  |
| 2925 | 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; orb) for internal use; orc) contains 0.05% or less of lemon oil; ord) for use in soaps or bath or shower gels that are washed off the skin. |
| 2926 | LEMON OIL DISTILLED | A,E,H | When used internally, oxedrine is a mandatory component of lemon oil distilled.The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. |
| 2927 | 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. |
| 2928 | 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%. |
| 2929 | 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. |
| 2930 | LEMONGRASS OIL | A,E,H |  |
| 2931 | LENS CULINARIS | A,H |  |
| 2932 | LENTIL | E |  |
| 2933 | LENTINULA EDODES | A,E,H |  |
| 2934 | LEONTOPODIUM ALPINUM | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.The concentration in the medicine must be no more than 1%. |
| 2935 | LEONURUS CARDIACA | A,E,H |  |
| 2936 | LEONURUS SIBIRICUS | A,E,H |  |
| 2937 | LEPIDIUM APETALUM | A,H |  |
| 2938 | 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). |
| 2939 | LEPTOSPERMUM PETERSONII | E | Only for use in topical medicines for dermal application.The concentration in the medicine must be no more 5%. |
| 2940 | LEPTOSPERMUM SCOPARIUM OIL | A | Only for use as an active ingredient when the route of administration is topical or oral application in a mouthwash preparation. If the concentration is more than 25%, the nominal capacity of the container must be no more than 25mL. When the concentration is more than 25%, and the nominal capacity of the container less than 15mL, a restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label:- (CHILD) ‘Keep out of reach of children' (or word to that effect)- (NTAKEN) ‘Not to be taken’When the concentration is more than 25%, the nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label:- (CHILD) ‘Keep out of reach of children' (or word to that effect)- (NTAKEN) ‘Not to be taken’ |
| 2941 | LESPEDEZA CAPITATA | A,H |  |
| 2942 | LETTUCE | E |  |
| 2943 | LEUCINE | A,E |  |
| 2944 | LEUZEA UNIFLORUM | A,H |  |
| 2945 | LEVISTICUM OFFICINALE | A,H |  |
| 2946 | LEVOCARNITINE | A |  |
| 2947 | LEVOCARNITINE FUMARATE | A |  |
| 2948 | LEVOCARNITINE HYDROCHLORIDE | A |  |
| 2949 | LEVOCARNITINE MAGNESIUM CITRATE | A |  |
| 2950 | LEVOCARNITINE TARTRATE | A |  |
| 2951 | LEVOMEFOLATE CALCIUM | A, | Only for use in oral medicines.Levomefolic acid is a mandatory component of Levomefolate calcium.The maximum recommended daily dose must provide no more than 500 micrograms of Levomefolic acid from Levomefolate calcium.When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per maximum recommended daily dose.When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects:a) the maximum daily dose must provide 400 – 500 micrograms of folic acid; andb) the following statements must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)’; and - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet’. |
| 2952 | 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 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. When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects:a) the maximum daily dose must provide 400 – 500 micrograms of folic acid; andb) the following statements must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)’; and - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet’. |
| 2953 | LEVOTHYROXINE SODIUM | H | Only for use as an active homoeopathic ingredient. |
| 2954 | 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%.  |
| 2955 | LIGHT KAOLIN | E |  |
| 2956 | LIGHT LIQUID PARAFFIN | A,E | When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. |
| 2957 | LIGHT 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 light magnesium oxide.The percentage of magnesium from light magnesium oxide should be calculated based on the molecular weight of light magnesium oxide.The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use. |
| 2958 | LIGUSTICUM SINENSE | A,H |  |
| 2959 | LIGUSTICUM WALLICHII | A,E,H |  |
| 2960 | LIGUSTRUM LUCIDUM | A,H |  |
| 2961 | LILIUM BROWNII | A,H |  |
| 2962 | LILIUM CANDIDUM | A,E,H |  |
| 2963 | LILIUM LANCIFOLIUM | A,H |  |
| 2964 | LILIUM LONGIFLORUM | A,H |  |
| 2965 | LIME FRUIT | E |  |
| 2966 | 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%. |
| 2967 | 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; orb) contains 0.5% or less of lime oil coldpressed; orc) for use in soaps or bath or shower gels that are washed off the skin. |
| 2968 | LIME OIL DISTILLED | A,E,H |  |
| 2969 | 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%.  |
| 2970 | 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%. |
| 2971 | LIME TREE FLOWER DRY | A,H |  |
| 2972 | LIME TREE FLOWER POWDER | A,H |  |
| 2973 | LIME, ESSENCE | E |  |
| 2974 | 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%. |
| 2975 | LIMONENE | E | When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose. |
| 2976 | LINALOOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.If used in a flavour the total flavour concentration in a medicine must be no more than 5%.If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2977 | LINALOOL OXIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2978 | 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%. |
| 2979 | LINALYL ACETATE | E | Only for use in topical medicines for dermal application. |
| 2980 | 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%.  |
| 2981 | 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%. |
| 2982 | 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%. |
| 2983 | LINALYL FORMATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2984 | 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%. |
| 2985 | 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%. |
| 2986 | LINDERA STRYCHNIFOLIA | A,H |  |
| 2987 | 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%. |
| 2988 | LINOLEIC ACID | E |  |
| 2989 | LINOLENIC ACID | E |  |
| 2990 | LINSEED DRY | A,E,H |  |
| 2991 | LINSEED OIL | A,E,H |  |
| 2992 | LINSEED POWDER | A,E,H |  |
| 2993 | LINUM USITATISSIMUM | A,E,H |  |
| 2994 | LIPASE | A | Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guidelineWhen 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. |
| 2995 | LIQUID GLUCOSE | E | When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg 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). |
| 2996 | LIQUID PARAFFIN | A,E | When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. |
| 2997 | LIQUIDAMBAR FORMOSANA | A,H |  |
| 2998 | LIQUIDAMBAR ORIENTALIS | A,H |  |
| 2999 | LIQUIDAMBAR STYRACIFLUA | A,E,H |  |
| 3000 | LIQUIDAMBAR TAIWANIANA | A,H |  |
| 3001 | 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%. |
| 3002 | LIQUORICE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3003 | LIQUORICE DRY | A,E,H |  |
| 3004 | LIQUORICE LIQUID EXTRACT | A,E,H |  |
| 3005 | LIQUORICE POWDER | A,E,H |  |
| 3006 | LITCHI CHINENSIS | A,H |  |
| 3007 | LITHIUM CARBONATE | H |  Only for use as an active homoeopathic ingredient.  |
| 3008 | LITHOSPERMUM OFFICINALE | A,H | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale. |
| 3009 | LITSEA CUBEBA | A,E,H |  |
| 3010 | 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%. |
| 3011 | LOBARIA PULMONARIA | A,H |  |
| 3012 | 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.  |
| 3013 | LOBELIA INFLATA | A,H | The concentration in the medicine must be no more than 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.  |
| 3014 | 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.  |
| 3015 | LOLIUM PERENNE | A,H |  |
| 3016 | LOLIUM TEMULENTUM | A,H |  |
| 3017 | 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%. |
| 3018 | LONICERA CAPRIFOLIUM | A,E,H |  |
| 3019 | LONICERA JAPONICA | A,E,H |  |
| 3020 | LONICERA PERICLYMENUM | A,H |  |
| 3021 | LOPHATHERUM GRACILE | A,H |  |
| 3022 | LOQUAT | E |  |
| 3023 | LORANTHUS PARASITICUS | A,H |  |
| 3024 | LOROPETALUM CHINENSIS | A,H |  |
| 3025 | LOTUS CORNICULATUS | A,H |  |
| 3026 | 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 more than 5%.  |
| 3027 | LOVAGE OIL | A,E,H |  |
| 3028 | LOVAGE ROOT DRY | A,H |  |
| 3029 | LOVAGE ROOT POWDER | A,H |  |
| 3030 | LUDWIGIA PROSTRATA | A,H |  |
| 3031 | LUFFA CYLINDRICA | A,H |  |
| 3032 | LUFFA PURGANS | A,H |  |
| 3033 | LUTEIN | A,E,H | Permitted for use as a colour for oral and topical use.  |
| 3034 | LYCHEE | E |  |
| 3035 | LYCIUM BARBARUM | A,H |  |
| 3036 | LYCIUM CHINENSE | A,E,H |  |
| 3037 | LYCOPENE | A,E |  |
| 3038 | 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. |
| 3039 | LYCOPODIUM ANNOTINUM | A,H |  |
| 3040 | LYCOPODIUM CLAVATUM | A,H |  |
| 3041 | LYCOPODIUM COMPLANATUM | A,H |  |
| 3042 | LYCOPUS EUROPAEUS | A,H |  |
| 3043 | LYCOPUS LUCIDUS | A,H |  |
| 3044 | 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%.  |
| 3045 | LYGODIUM JAPONICUM | A,H |  |
| 3046 | LYSIMACHIA CHRISTINAE | A,H |  |
| 3047 | LYSIMACHIA VULGARIS | A,H |  |
| 3048 | LYSINE | A,E |  |
| 3049 | LYSINE HYDROCHLORIDE | A,E |  |
| 3050 | LYTHRUM HYSSOPIFOLIA | A,H |  |
| 3051 | LYTHRUM SALICARIA | A,H |  |
| 3052 | LYTHRUM VERTICILLATUM | A,H |  |
| 3053 | MACADAMIA INTEGRIFOLIA | A,E |  |
| 3054 | MACADAMIA NUT | E |  |
| 3055 | MACADAMIA NUT OIL | E |  |
| 3056 | MACADAMIA TERNIFOLIA | A,E,H |  |
| 3057 | MACE | E,H | Only for use as an active homoeopathic ingredient. Safrole is a mandatory component of Mace.When used internally, the concentration of safrole in the medicine must be no more than 0.1%.When used topically, the concentration of safrole in the medicine must be no more than 1.0%. |
| 3058 | 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. |
| 3059 | MACROCYSTIS PYRIFERA | A,E,H | Iodine is a mandatory component of Macrocystis pyrifera.Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use. |
| 3060 | MACROGOL 1000 | E |  |
| 3061 | MACROGOL 1450 | E | Only for use in topical medicines for dermal application. |
| 3062 | MACROGOL 1500 | E |  |
| 3063 | 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%. |
| 3064 | MACROGOL 200 | E | Only for use in topical medicines for dermal application. |
| 3065 | MACROGOL 20000 | E |  |
| 3066 | MACROGOL 300 | E |  |
| 3067 | MACROGOL 3000 | E |  |
| 3068 | MACROGOL 3350 | A,E | When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time. |
| 3069 | MACROGOL 40 | E | Only for use in topical medicines for dermal application. |
| 3070 | MACROGOL 400 | E |  |
| 3071 | MACROGOL 4000 | E |  |
| 3072 | MACROGOL 45000 | E | Only for use in topical medicines for dermal application. |
| 3073 | MACROGOL 600 | E |  |
| 3074 | MACROGOL 6000 | E |  |
| 3075 | MACROGOL 600000 | E |  |
| 3076 | MACROGOL 800 | E |  |
| 3077 | MACROGOL 8000 | E |  |
| 3078 | 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%. |
| 3079 | MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER | E | Only for use in oral medicines.The concentration in the medicine must be no more than 5%. |
| 3080 | 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. |
| 3081 | 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 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. |
| 3082 | 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. |
| 3083 | MAGNESIUM ASCORBYL PHOSPHATE | E | Only for use in topical medicines for dermal application. |
| 3084 | 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. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.- |
| 3085 | 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. |
| 3086 | 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. |
| 3087 | 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 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. |
| 3088 | 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. |
| 3089 | 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. |
| 3090 | 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. |
| 3091 | 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 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. |
| 3092 | 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. |
| 3093 | 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. |
| 3094 | 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 permitted when the medicine is for oral or sublingual use. |
| 3095 | 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. |
| 3096 | 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. |
| 3097 | MAGNESIUM GLYCINATE DIHYDRATE | 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 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.  |
| 3098 | MAGNESIUM HYDROGEN PHOSPHATE | H |  |
| 3099 | MAGNESIUM HYDROXIDE | A,E | When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. |
| 3100 | 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. |
| 3101 | 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. |
| 3102 | MAGNESIUM NITRATE | E | Only for use in topical medicines for dermal application. |
| 3103 | 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. |
| 3104 | 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 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. |
| 3105 | 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. |
| 3106 | 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 phosphate pentahydrate.The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use. |
| 3107 | MAGNESIUM PHOSPHATE TRIBASIC | A,E,H | Magnesium is a mandatory component of Magnesium phosphate tribasic.The percentage of magnesium from magnesium phosphate tribasic should be calculated based on the molecular weight of magnesium phosphate tribasic. |
| 3108 | 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. |
| 3109 | MAGNESIUM STEARATE | E |  |
| 3110 | 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. |
| 3111 | MAGNESIUM SULFATE HEPTAHYDRATE | 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 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. |
| 3112 | 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. |
| 3113 | 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 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. |
| 3114 | MAGNESIUM TRISILICATE | E |  |
| 3115 | MAGNOLIA GLAUCA | A,H |  |
| 3116 | MAGNOLIA LILIFLORA | A,H |  |
| 3117 | MAGNOLIA OBOVATA | A,H |  |
| 3118 | MAGNOLIA OFFICINALIS | A,E,H |  |
| 3119 | MAGNOLIA SALICIFOLIA | A,H |  |
| 3120 | MAIZE | E |  |
| 3121 | MAIZE BRAN | E |  |
| 3122 | MAIZE OIL | A,E,H |  |
| 3123 | MAIZE STARCH | A,E,H |  |
| 3124 | MALACHITE GREEN | E | Permitted for use as a colour for topical use. |
| 3125 | 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. |
| 3126 | MALPIGHIA GLABRA | A,E,H |  |
| 3127 | MALT EXTRACT | E |  |
| 3128 | 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]’.  |
| 3129 | 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).  |
| 3130 | 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 requires the following warning statement on the medicine label:- (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect). |
| 3131 | MALTOL | E |  |
| 3132 | 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%.  |
| 3133 | 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). |
| 3134 | MALUS DOMESTICA | A,E,H | The concentration of amygdalin in the medicine must be no more than 0%. |
| 3135 | MALUS PUMILA | A,E,H |  |
| 3136 | MALUS SYLVESTRIS | A,H |  |
| 3137 | MALVA MOSCHATA | A,H |  |
| 3138 | MALVA SYLVESTRIS | A,E,H |  |
| 3139 | MALVA VERTICILLATA | A,H |  |
| 3140 | MANDARIN | E |  |
| 3141 | 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%. |
| 3142 | 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. |
| 3143 | 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%. |
| 3144 | MANDARIN RESIDUE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3145 | 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%. |
| 3146 | 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%. |
| 3147 | MANGANESE | H | Only for use as an active homoeopathic ingredient. |
| 3148 | 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 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. |
| 3149 | 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. |
| 3150 | MANGANESE ACETATE TETRAHYDRATE | H | Only for use as an active homoeopathic ingredient.  |
| 3151 | 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 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. |
| 3152 | 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. |
| 3153 | 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 mineral) supplementation' is only permitted when the medicine is for oral or sublingual use. |
| 3154 | 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. |
| 3155 | 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. |
| 3156 | 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 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. |
| 3157 | 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. |
| 3158 | 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. |
| 3159 | MANGIFERA INDICA | A,E,H |  |
| 3160 | MANGO | E,H |  |
| 3161 | MANIHOT UTILISSIMA | A,H |  |
| 3162 | 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). |
| 3163 | MARANTA ARUNDINACEA | A,H |  |
| 3164 | MARINE SPONGE | H | Only for use as an active homoeopathic ingredient. |
| 3165 | 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). |
| 3166 | 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). |
| 3167 | MARRUBIUM VULGARE | A,E,H |  |
| 3168 | MARSDENIA CUNDURANGO | A,H |  |
| 3169 | MARSHMALLOW ROOT DRY | A,H |  |
| 3170 | MARSHMALLOW ROOT POWDER | A,H |  |
| 3171 | MARTYNIA PARVIFLORA | A,H |  |
| 3172 | 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%.  |
| 3173 | MASTIC | A,H |  |
| 3174 | 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%. |
| 3175 | MATRICARIA CHAMOMILLA | A,E,H |  |
| 3176 | MATRICARIA FLOWER DRY | A,E,H |  |
| 3177 | MATRICARIA RECUTITA | A,E,H |  |
| 3178 | MEADOWSWEET HERB DRY | A,H |  |
| 3179 | MEADOWSWEET HERB POWDER | A,H |  |
| 3180 | MECOBALAMIN (CO-METHYLCOBALAMIN) | A | Only for use in oral medicines. |
| 3181 | 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. |
| 3182 | MEDIUM CHAIN TRIGLYCERIDES | E |  |
| 3183 | MELALEUCA ALTERNIFOLIA | A,E,H | Cineole is a mandatory component of Melaleuca alternifolia.In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; andc) the container must include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure. |
| 3184 | MELALEUCA CAJUPUTI | A,E,H | Cineole is a mandatory component of Melaleuca cajuputi.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; andc) the container must include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure. |
| 3185 | MELALEUCA DISSITIFLORA | A,H | Cineole is a mandatory component of Melaleuca dissitiflora.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; andc) the container must include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure. |
| 3186 | MELALEUCA ERICIFOLIA | A,E,H | Cineole is a mandatory component of Melaleuca ericifolia.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; andc) the container must include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure. |
| 3187 | MELALEUCA LINARIIFOLIA | A,H | Cineole is a mandatory component of Melaleuca linariifolia.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; andc) the container must include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure. |
| 3188 | MELALEUCA OIL | A,E,H | Cineole and cajuput oil are a mandatory components of Melaleuca Oil.When the plant preparation is oil and the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label:- (CHILD) ‘Keep out of reach of children’ (or word to that effect)- (NTAKEN) ‘Not to be taken’. When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container. Where the nominal capacity of the container is more than 15 mL but less than or equal to 25 mL, then a child resistant closure and restricted flow insert must be fitted on the container. |
| 3189 | MELALEUCA QUINQUENERVIA | A,E,H | Cineole is a mandatory component of Melaleuca quinquenervia.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; andc) the container must include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure. |
| 3190 | MELICOPE PTELEIFOLIA | A,H |  |
| 3191 | 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%. |
| 3192 | MELISSA OFFICINALIS | A,E,H |  |
| 3193 | MELON | E |  |
| 3194 | MENADIONE SODIUM BISULFITE | E |  |
| 3195 | 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.  |
| 3196 | MENISPERMUM CANADENSE | A,H |  |
| 3197 | MENTHA AQUATICA | A,H |  |
| 3198 | MENTHA ARVENSIS | A,E,H |  |
| 3199 | 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%. |
| 3200 | 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%.  |
| 3201 | MENTHA HAPLOCALYX | A,E,H |  |
| 3202 | 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 millilitres, the concentration of D-pulegone in the medicine must be no more than 4%.When the concentration of D-Pulegone in the preparation is more than 4% and the nominal capacity of the container is 15 millilitres or less, the medicine must have a child resistant closure and restricted flow insert fitted on the container. The medicine requires the following warning statements on the medicine label:- (NTAKEN) 'Not to be taken'- (CHILD) 'Keep out of reach of children' (or words to that effect).When the medicine is for topical use, the maximum recommended daily dose must be no more than 150 mg of Mentha pulegium oil or distillate.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 or distillate. |
| 3203 | MENTHA SPICATA | A,E,H |  |
| 3204 | MENTHA X CARDIACA | A,E,H |  |
| 3205 | MENTHA X PIPERITA | A,E,H |  |
| 3206 | MENTHA X PIPERITA NOTHOSUBSP. CITRATA | A,H |  |
| 3207 | 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%.  |
| 3208 | 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%. |
| 3209 | 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%.  |
| 3210 | MENTHOL | A,E | When used as an active ingredient, permitted only in medicated space sprays and medicated lozenges.  |
| 3211 | 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%. |
| 3212 | 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%.  |
| 3213 | 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%.  |
| 3214 | MENTHOXYPROPANEDIOL | E | For oral use only.The concentration in the medicine must be no more than 0.04%. |
| 3215 | 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%.  |
| 3216 | 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%.  |
| 3217 | 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%. |
| 3218 | 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%.  |
| 3219 | MENTHYL LACTATE | E |  |
| 3220 | MENYANTHES TRIFOLIATA | A,H |  |
| 3221 | MERCURIC CHLORIDE | H | Only for use as an active homoeopathic ingredient. |
| 3222 | MERCURY | H | Only for use as an active homoeopathic ingredient. |
| 3223 | MESPILUS GERMANICA | A,H |  |
| 3224 | METACRESOL | E | Only for use in topical medicines for dermal application. |
| 3225 | METHACRYLIC ACID COPOLYMER | E | Only for use in oral medicines.  |
| 3226 | 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%. |
| 3227 | 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%. |
| 3228 | METHIONINE | A,E |  |
| 3229 | METHYL-3-METHYLTHIOPROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3230 | 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%.  |
| 3231 | 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%.  |
| 3232 | 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%. |
| 3233 | 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%. |
| 3234 | METHYL 3,6-DIMETHYLRESORCYLATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3235 | 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%. |
| 3236 | 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%. |
| 3237 | METHYL ACETYL RICINOLEATE | E | Only for use in topical medicines for dermal application. |
| 3238 | 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%. |
| 3239 | 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%. |
| 3240 | METHYL BENZOATE | E | Only for use in topical medicines for dermal application. |
| 3241 | 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%.  |
| 3242 | 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%.  |
| 3243 | 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%. |
| 3244 | 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%. |
| 3245 | 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%. |
| 3246 | 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%. |
| 3247 | 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%.  |
| 3248 | 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%. |
| 3249 | 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%. |
| 3250 | METHYL DI-TERT-BUTYL-4-HYDROXYHYDROCINNAMATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3251 | 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%. |
| 3252 | 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%.  |
| 3253 | METHYL ETHER | E | Only for use in topical medicines for dermal application. |
| 3254 | 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%. |
| 3255 | 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%. |
| 3256 | 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%.  |
| 3257 | 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. |
| 3258 | METHYL GLUCETH-20 | E | Only for use in topical medicines for dermal application. |
| 3259 | 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%. |
| 3260 | METHYL GLUCETH-20 SESQUIHYDRATE | E | Only for use in topical medicines for dermal application. |
| 3261 | METHYL GLUCOSE DIOLEATE | E | Only for use in topical medicines for dermal application. |
| 3262 | METHYL GLUCOSE SESQUIOLEATE | E | Only for use in topical medicines for dermal application. |
| 3263 | METHYL GLUCOSE SESQUISTEARATE | E | Only for use in topical medicines for dermal application. |
| 3264 | 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%. |
| 3265 | 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%. |
| 3266 | 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%.  |
| 3267 | 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%. |
| 3268 | METHYL HYDROGENATED ROSINATE | E | Only for use in topical medicines for dermal application. |
| 3269 | METHYL HYDROJASMONATE | E | Only for use in topical medicines for dermal application. |
| 3270 | METHYL HYDROXYBENZOATE | E | Medicines containing hydroxybenzoates require the following warning statement on the medicine label:- (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved name of hydroxybenzoate used]’ (or words to this effect) if product contains one hydroxybenzoate source. |
| 3271 | 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%. |
| 3272 | 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%. |
| 3273 | 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%. |
| 3274 | METHYL ISOVALERATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3275 | 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%.  |
| 3276 | 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%. |
| 3277 | 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%. |
| 3278 | 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%. |
| 3279 | 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%.  |
| 3280 | METHYL METHACRYLATE | E |  |
| 3281 | 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. The concentration in the medicine must be no more than 1%. |
| 3282 | 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%. |
| 3283 | 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%. |
| 3284 | 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%. |
| 3285 | 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%. |
| 3286 | METHYL NONYLENATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3287 | METHYL OCTIN CARBONATE | E |  |
| 3288 | 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%. |
| 3289 | 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%.  |
| 3290 | 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%.  |
| 3291 | 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%. |
| 3292 | METHYL PHENYLACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3293 | 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%. |
| 3294 | 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%. |
| 3295 | 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 dosage unit, and actuation of the spay device is ergonomically difficult for young children to accomplish. |
| 3296 | METHYL STEARATE | E |  |
| 3297 | 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%.  |
| 3298 | 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%. |
| 3299 | 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%. |
| 3300 | METHYLCELLULOSE | A,E |  |
| 3301 | METHYLCHLOROISOTHIAZOLINONE | E | Only for use in topical medicines for dermal application.The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%. |
| 3302 | 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%. |
| 3303 | METHYLDIBROMO GLUTARONITRILE | E | Only for use in topical medicines for dermal application. |
| 3304 | 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%. |
| 3305 | METHYLISOTHIAZOLINONE | E | Only for use in topical medicines for dermal application.The concentration of methylisothiazolinone in the medicine must be no more than 0.01%.The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%. |
| 3306 | 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%.  |
| 3307 | 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%. |
| 3308 | 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%. |
| 3309 | METHYLSTYRENE/VINYLTOLUENE COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 3310 | MICA | E | Only for use when the route of administration is oral, dental or topical. The concentration in oral medicines must be no more than 2.5%.The concentration in dental toothpastes must be no more than 0.5%.  |
| 3311 | MICROCALICIUM ARENARIUM | A,H |  |
| 3312 | 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%.  |
| 3313 | MICROCOS PANICULATA | A,H |  |
| 3314 | MICROCRYSTALLINE CELLULOSE | E |  |
| 3315 | MICROCRYSTALLINE WAX | E | Only for use as an excipient in medicines for topical, oral or oral application routes of administration.When microcrystalline wax is used as an excipient ingredient, the route of administration 'oral' is only permitted when the dosage form is 'chewing gum'. |
| 3316 | MICROSPORUM GYPSEUM | A,H |  |
| 3317 | MILK FAT | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3318 | MILK THISTLE FRUIT DRY | A,H |  |
| 3319 | MILK THISTLE FRUIT POWDER | A,H |  |
| 3320 | MILLET | E |  |
| 3321 | MILLETTIA DIELSIANA | A,H |  |
| 3322 | 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%.  |
| 3323 | MIMULUS GUTTATUS | A,H |  |
| 3324 | MINT OIL DEMENTHOLISED | A,E,H |  |
| 3325 | 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%.  |
| 3326 | MITCHELLA REPENS | A,H |  |
| 3327 | MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE | 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.’ |
| 3328 | MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE | 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.’ |
| 3329 | 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%. |
| 3330 | MODIFIED FOOD STARCH | E |  |
| 3331 | MOLASSES | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3332 | 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. |
| 3333 | MOLYBDENUM TRIOXIDE | A | Molybdenum is a mandatory component of Molybdenum trioxide.The maximum daily dose of molybdenum from Molybdenum trioxide must be no more than 125 micrograms.The percentage of molybdenum from molybdenum trioxide should be calculated based on the molecular weight of molybdenum trioxide. |
| 3334 | MOMORDICA BALSAMINA | A,H |  |
| 3335 | MOMORDICA CHARANTIA | A,H |  |
| 3336 | 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.  |
| 3337 | MONARDA DIDYMA | A,H |  |
| 3338 | MONO- AND DI- GLYCERIDES | E |  |
| 3339 | MONOBASIC AMMONIUM PHOSPHATE | E | Only for use in topical medicines for dermal application. |
| 3340 | MONOBASIC CALCIUM PHOSPHATE | A,E,H | When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of monobasic calcium phosphate.The percentage of calcium from monobasic calcium phosphate should be calculated based on the molecular weight of monobasic calcium phosphate.The following indications are only permitted when the medicine is for oral and sublingual use:- (OSPOR1) ‘Source of calcium. May assist in the prevention and/or treatment of osteoporosis’- (OSPOR2) ‘Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis’- (CALC1) ‘Source of calcium. Women's calcium requirements are increased after menopause’- (CALC2) ‘Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults’- (CALC3) ‘Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone’- (CALC4) ‘Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.’The indication ‘For mineral (may state the mineral) supplementation’ is only permitted for use when the medicine is for oral or sublingual use. |
| 3341 | MONOBASIC DIHYDRATE SODIUM PHOSPHATE | E | When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect). |
| 3342 | MONOBASIC POTASSIUM PHOSPHATE | A,E,H | When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of monobasic potassium phosphate.The percentage of potassium from monobasic potassium phosphate should be calculated based on the molecular weight of monobasic potassium phosphate.When used in a solid medicine containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5.When used in a liquid or a semi-solid medicine containing this ingredient, the pH of the medicine must be no more than 11.5.The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use. |
| 3343 | 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 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. |
| 3344 | MONOETHANOLAMINE | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%. |
| 3345 | 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 should not replace a balanced diet.’ |
| 3346 | 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.’ |
| 3347 | MONOPOTASSIUM GLUTAMATE | A,E |  |
| 3348 | 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).’ |
| 3349 | MONOSODIUM GLUTAMATE MONOHYDRATE | A,E |  |
| 3350 | MONSTERA DELICIOSA | A,H |  |
| 3351 | MONTAN WAX | E |  |
| 3352 | 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%. |
| 3353 | 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). |
| 3354 | MORINDA OFFICINALIS | A,H |  |
| 3355 | MORINGA OLEIFERA | A,H |  |
| 3356 | MORUS ALBA | A,H |  |
| 3357 | MORUS BOMBYCIS | A,H |  |
| 3358 | MORUS NIGRA | A,E,H |  |
| 3359 | 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%. |
| 3360 | MOTHERWORT HERB DRY | A,H |  |
| 3361 | MOTHERWORT HERB POWDER | A,H |  |
| 3362 | 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%. |
| 3363 | MULBERRY | E |  |
| 3364 | MUNG BEAN | E |  |
| 3365 | MURRAYA KOENIGII | A,H |  |
| 3366 | MURRAYA PANICULATA | A,H |  |
| 3367 | MUSA X PARADISIACA | A,H |  |
| 3368 | MUSK KETONE | E | Only for use in topical medicines for dermal application. |
| 3369 | 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%. |
| 3370 | MUSK XYLOL | E | Only for use in topical medicines for dermal application. |
| 3371 | MUSKS | H | Only for use as an active homoeopathic ingredient.  |
| 3372 | MUSTARD | E | Allyl isothiocyanate is a mandatory component of Mustard.The maximum daily dose must not provide more than 20 mg of allyl isothiocyanate.  |
| 3373 | 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.  |
| 3374 | 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.  |
| 3375 | MYOSOTIS ARVENSIS | A,H |  |
| 3376 | 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%. |
| 3377 | 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%. |
| 3378 | MYRICA CERIFERA | A,E,H |  |
| 3379 | MYRISTIC ACID | E |  |
| 3380 | 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%. |
| 3381 | MYRISTICA FRAGRANS | A,E,H | Safrole is a mandatory component of Myristica fragrans.When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.When for topical use then the concentration of safrole in the medicine must be no more than 1%.When the plant preparation is oil or distillate and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or word to that effect). |
| 3382 | MYRISTYL ALCOHOL | E | Only for use in topical medicines for dermal application. |
| 3383 | MYRISTYL LACTATE | E | Only for use in topical medicines for dermal application. |
| 3384 | MYRISTYL MYRISTATE | E | Only for use in topical medicines for dermal application. |
| 3385 | MYROXYLON BALSAMUM | A,E,H |  |
| 3386 | MYROXYLON BALSAMUM VAR. PEREIRAE | A,H |  |
| 3387 | MYRRH | A,H |  |
| 3388 | MYRRH OIL | A,E,H |  |
| 3389 | MYRRH RESIN | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3390 | MYRRHIS ODORATA | A,H |  |
| 3391 | MYRSINE AFRICANA | A,H |  |
| 3392 | 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%.  |
| 3393 | 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%.  |
| 3394 | 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%. |
| 3395 | 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%. |
| 3396 | MYRTUS COMMUNIS | A,E,H |  |
| 3397 | N-BUTYL SULFIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3398 | 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%.  |
| 3399 | 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%. |
| 3400 | NAPHTHALENE | H | Only for use as an active homoeopathic ingredient.  |
| 3401 | NARDOSTACHYS CHINENSIS | A,H |  |
| 3402 | 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%.  |
| 3403 | NASTURTIUM OFFICINALE | A,E,H |  |
| 3404 | 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 more than 5%. |
| 3405 | NATURAL FISH OIL | A,E | When therapeutic indications for this product are made against Vitamin A or colecalciferol (Vitamin D), they are mandatory components of fish oil - natural.When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose.Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose.When for use in adults the medicine requires the following warning statements on the medicine label:- (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your effect].' NOTE: Position this warning at the beginning of the directions for use.- (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use.- (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D.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 'Vitamin D helps calcium absorption (or words of like intent)' and 'A diet deficient in calcium can lead to osteoporosis in later life' are permitted only for oral use. |
| 3406 | NAUCLEA OFFICINALIS | A,H |  |
| 3407 | NELUMBO NUCIFERA | A,H |  |
| 3408 | 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%. |
| 3409 | 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% |
| 3410 | 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%.  |
| 3411 | 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%. |
| 3412 | 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%.  |
| 3413 | 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%. |
| 3414 | NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE | E | Only for use in topical medicines for dermal application. |
| 3415 | NEOPICRORHIZA SCROPHULARIIFLORA | A,H |  |
| 3416 | 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%. |
| 3417 | 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%.  |
| 3418 | 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%. |
| 3419 | 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%. |
| 3420 | 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%. |
| 3421 | 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%.  |
| 3422 | 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%. |
| 3423 | N-GLUCONYL ETHANOLAMINE | E | Permitted for use only in combination with other permitted ingredients as a flavour.If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3424 | NICKEL | H | Only for use as an active homoeopathic ingredient.  |
| 3425 | NICOTIANA TABACUM | H | Only for use as an active homoeopathic ingredient.  |
| 3426 | 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:- (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet.’ |
| 3427 | 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.’ |
| 3428 | 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.’ |
| 3429 | NIGELLA DAMASCENA | A,H |  |
| 3430 | NIGELLA SATIVA | A,E,H |  |
| 3431 | NIGRITELLA ANGUSTIFOLIA | A,H |  |
| 3432 | 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%. |
| 3433 | 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%. |
| 3434 | 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%. |
| 3435 | 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%. |
| 3436 | NONFAT DRY MILK | E,H | If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label:- (LACT) 'Contains lactose' (or words to that effect). |
| 3437 | 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%.  |
| 3438 | NONOXINOL 10 | E | Only for use in topical medicines for dermal application. |
| 3439 | 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%. |
| 3440 | 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%. |
| 3441 | NONOXINOL 9 | E | Only for use in topical medicines for dermal application.The concentration in the medicine must be no more than 25%. |
| 3442 | 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%. |
| 3443 | 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%.  |
| 3444 | NOPYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3445 | 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%. |
| 3446 | NOTOPTERYGIUM FORBESII | A,H |  |
| 3447 | NOTOPTERYGIUM INCISIUM | A,H |  |
| 3448 | NUPHAR JAPONICA | A,H |  |
| 3449 | NUPHAR LUTEA | A,H |  |
| 3450 | 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%. |
| 3451 | NUTMEG OIL | A,E,H | Safrole is a mandatory component of Nutmeg oil. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.When the concentration of Nutmeg oil in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, the medicine must have a restricted flow insert fitted on the container and requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).  |
| 3452 | 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%. |
| 3453 | 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%. |
| 3454 | 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%.  |
| 3455 | NYCTANTHES ARBOR-TRISTIS | A,H |  |
| 3456 | NYLON | E | Only for use in topical medicines for dermal application. |
| 3457 | NYLON-12 | E | Only for use in topical medicines for dermal application. |
| 3458 | NYLON 6/12 | E | Only for use in topical medicines for dermal application. |
| 3459 | NYMPHAEA ALBA | A,E,H |  |
| 3460 | 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. |
| 3461 | NYMPHAEA ODORATA | A,H |  |
| 3462 | 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%.  |
| 3463 | 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%. |
| 3464 | OAKMOSS ABSOLUTE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3465 | 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). |
| 3466 | 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). |
| 3467 | 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:- (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect). |
| 3468 | 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%. |
| 3469 | 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%. |
| 3470 | OCIMUM BASILICUM | A,E,H | When the plant preparation is oil or distillate, Methyl chavicol, eugenol, methyleugenol and cineole are mandatory components of Ocimum basilicum.The concentration of methyleugenol in the medicine must not exceed 1%.When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25 millilitres.When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25 millilitres or less, a restricted flow insert must be fitted on the container, and requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).When the concentration of cineole OR eugenol in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres and the following warning statements must be included on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.When the concentration of cineole OR eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of cineole OR eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container.When the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of eugenol and the concentration of eugenol in the product must not be greater than 25%. |
| 3471 | OCIMUM KILIMANDSCHARICUM | A,H | Camphor is a mandatory component of Ocimum kilimandscharicum.In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must also have a child resistant closure fitted on the container. |
| 3472 | OCIMUM MINIMUM | A,H |   |
| 3473 | OCIMUM TENUIFLORUM | A,H | When the plant part is oil or distillate, eugenol is a mandatory component of Ocimum tenuiflorum.When the concentration of eugenol in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres and the following warning statements must be included on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'.When the concentration of eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container.When the preparation is for topical use in the mouth, the preparation may not contain more than 5 mL of eugenol and the concentration of eugenol in the product must not be greater than 25%. |
| 3474 | 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%. |
| 3475 | OCTACOSANOL | E |  |
| 3476 | 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%. |
| 3477 | OCTADECENE/MA COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 3478 | 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%. |
| 3479 | 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%. |
| 3480 | 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%. |
| 3481 | OCTANAL DIMETHYL ACETAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3482 | 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%. |
| 3483 | 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). |
| 3484 | OCTHILINONE | E | Only for use in topical medicines for dermal application. |
| 3485 | 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%. |
| 3486 | OCTOXINOL 10 | E | Only for use in topical medicines for dermal application. |
| 3487 | OCTYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3488 | OCTYL HYDROXYSTEARATE | E | Only for use in topical medicines for dermal application. |
| 3489 | 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%.  |
| 3490 | OCTYL ISONONANOATE | E | Only for use in topical medicines for dermal application. |
| 3491 | 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%. |
| 3492 | OCTYL PALMITATE | E | Only for use in topical medicines for dermal application. |
| 3493 | 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%. |
| 3494 | OCTYL STEARATE | E | Only for use in topical medicines for dermal application. |
| 3495 | 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). |
| 3496 | OCTYLDODECANOL | E | Only for use in topical medicines for dermal application. |
| 3497 | 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. |
| 3498 | 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%. |
| 3499 | OCTYLDODECYL NEOPENTANOATE | E | Only for use in topical medicines for dermal application. |
| 3500 | OCTYLDODECYL STEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.The concentration in the medicine must be no more than 2%. |
| 3501 | 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%. |
| 3502 | 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. |
| 3503 | OENANTHE CROCATA | A,H | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material. |
| 3504 | OENOTHERA BIENNIS | A,E,H |  |
| 3505 | OENOTHERA STRICTA | A,H |  |
| 3506 | OKOUBAKA AUBREVILLEI | A,H |  |
| 3507 | OLDENLANDIA DIFFUSA | A,E,H |  |
| 3508 | OLEA EUROPAEA | A,E,H |  |
| 3509 | OLEIC ACID | E |  |
| 3510 | OLETH-10 | E | Only for use in topical medicines for dermal application. |
| 3511 | OLETH-2 | E | Only for use in topical medicines for dermal application.Dioxane and Ethylene oxide are mandatory components of Oleth-2.The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%. |
| 3512 | OLETH-20 | E | Only for use in topical medicines for dermal application. |
| 3513 | OLETH-3 | E | Only for use in topical medicines for dermal application. |
| 3514 | 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%.  |
| 3515 | OLETH-5 | E | Only for use in topical medicines for dermal application. |
| 3516 | OLEYL ALCOHOL | E | Only for use in topical medicines for dermal application. |
| 3517 | OLIBANUM OIL | A,E,H |  |
| 3518 | OLIGOFRUCTOSE | A,E |  |
| 3519 | OLIVE | E |  |
| 3520 | OLIVE OIL | A,E,H |  |
| 3521 | OMEGA-3-ACID ETHYL ESTERS 90 | A | Only for use in oral medicines.The maximum recommended daily dose must not exceed 4000 mg of Omega-3-acid ethyl esters 90, AND must not provide more than 3750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids.The medicine requires the following warning statements on the medicine label:-‘Individuals taking anticoagulants should seek medical advice before taking this product’ (or words to that effect).-‘To be taken with food’ (or words to that effect).- 'Not recommended for used by pregnant and lactating women' (or words to that effect).- 'Use in children under 12 years is not recommended' (or words to that effect). |
| 3522 | 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). |
| 3523 | ONION | E |  |
| 3524 | ONION OIL | A,H |  |
| 3525 | ONONIS SPINOSA | A,E,H |  |
| 3526 | ONOPORDON ACANTHIUM | A,H |  |
| 3527 | ONOSMODIUM VIRGINIANUM | A,H |  |
| 3528 | OPHIOPOGON JAPONICUS | A,H |  |
| 3529 | OPOPANAX CHIRONIUM | A,H |  |
| 3530 | OPOPANAX OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3531 | OPUNTIA FICUS-INDICA | A,H |  |
| 3532 | ORANGE | E |  |
| 3533 | 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%. |
| 3534 | 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. |
| 3535 | 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%.  |
| 3536 | ORANGE JUICE OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3537 | 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. |
| 3538 | 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%. |
| 3539 | 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; orb) in preparations containing 1.4% or less of orange oil bitter coldpressed; orc) for use in soaps or bath or shower gels that are washed off the skin. |
| 3540 | 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%. |
| 3541 | 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. |
| 3542 | 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%. |
| 3543 | 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. |
| 3544 | ORANGE PEEL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3545 | 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. |
| 3546 | 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%. |
| 3547 | ORANGE ROUGHY OIL | E | Only for use in topical medicines for dermal application. |
| 3548 | OREODAPHNE CALIFORNICA | A,H |  |
| 3549 | ORIGANUM MAJORANA | A,H | When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 50 millilitres. When the concentration of Origanum majorana oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect) |
| 3550 | 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%. |
| 3551 | ORIGANUM OIL SPANISH | A,E,H |  |
| 3552 | ORIGANUM VULGARE | A,E,H |  |
| 3553 | ORNITHINE | A,E |  |
| 3554 | ORNITHINE ASPARTATE | A,E |  |
| 3555 | ORNITHINE MONOHYDROCHLORIDE | A,E |  |
| 3556 | ORNITHOGALUM UMBELLATUM | A,H |  |
| 3557 | OROSTACHYS FIMBRIATA | A,H |  |
| 3558 | OROXYLUM INDICUM | A,H |  |
| 3559 | 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%.  |
| 3560 | 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%.  |
| 3561 | 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%.  |
| 3562 | ORRIS ROOT OIL | A,E,H |  |
| 3563 | ORRIS ROOT RESIN | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3564 | 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%. |
| 3565 | 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%. |
| 3566 | ORTHOSIPHON ARISTATUS | A,H |   |
| 3567 | ORYZA SATIVA | A,E,H |  |
| 3568 | ORYZANOL | E |  |
| 3569 | OSBECKIA CHINENSIS | A,H |  |
| 3570 | 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%.  |
| 3571 | OSMANTHUS FRAGRANS | E | Permitted for use only in combination with other permitted ingredients as a flavour.If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3572 | OTTELIA ALISMOIDES | A,H |  |
| 3573 | 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%. |
| 3574 | OXACYCLOHEXADECAN-2-ONE | E | Only for use in topical medicines for dermal application. |
| 3575 | 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%. |
| 3576 | OXALIC ACID | H | Only for use as an active homoeopathic ingredient.  |
| 3577 | OXALIS ACETOSELLA | A,H |  |
| 3578 | OXIDISED MAIZE STARCH | E | Permitted for use only in combination with other permitted ingredients as a flavour.If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3579 | OXIDISED TAPIOCA STARCH | E |  |
| 3580 | 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%. |
| 3581 | OYSTER | E |  |
| 3582 | OYSTER SHELL | A,E,H |  |