

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

Note: See sections 5 and 6.

| Permissible ingredients and requirements |                    |          |  |
|--|--------------------|----------|--|
| Column 1                                 | Column 2           | Column 3 | Column 4   |
| Item                                     | Ingredient name    | Purpose  | Specific requirements  |
| 2856                                     | KADSURA COCCINEA   | A, H     |  |
| 2857                                     | KAEMPFERIA GALANGA | A, H     |  |
| 2858                                     | KALMIA LATIFOLIA   | A, H     | <p>Beta-arbutin is a mandatory component of <i>Kalmia latifolia</i>.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> |
| 2859                                     | KAOLIN             | E        |  |
| 2860                                     | KELP DRY           | A, H     | <p>Iodine is a mandatory component of Kelp dry.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per</p>   |

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| <b>Item</b>                                     | <b>Ingredient name</b> | <b>Purpose</b>  | <b>Specific requirements</b>   |
|   |                        |                 | maximum recommended daily dose.  |
| 2861  | KELP POWDER            | A, E, H         | Iodine is a mandatory component of Kelp powder.<br>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.<br>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 2862  | KERATIN                | E               | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%.  |
| 2863  | KEROSENE               | E, H            | Only for use as a homoeopathic ingredient.<br>When used in liquid preparations, the concentration in the medicine must be no more than 25%.  |
| 2864  | KHAYA SENEGALENSIS     | A, E            | The maximum daily dose of the medicine must not contain more than the equivalent of 1 g dry bark of Khaya senegalensis.<br>The following warning statements are required on the medicine label:<br>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);                  |

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|   |                            |                 | - (LONGUSE) 'Not for prolonged use. May harm liver';<br>- (GEN2) 'If symptoms persist, seek the advice of a healthcare professional';<br>- (CHILD3) 'Use in children under 12 years is not recommended'; and<br>- (7DAYS) 'Do not use for more than 7 days'.  |
| 2865  | KIDNEY BEAN                | E               |   |
| 2866  | KIRSCH                     | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 2867  | KIWI FRUIT                 | E               |   |
| 2868  | KNAUTIA ARVENSIS           | A, H            |   |
| 2869  | KOREAN GINSENG ROOT DRY    | A, H            |   |
| 2870  | KOREAN GINSENG ROOT POWDER | A, H            |   |
| 2871  | KRAMERIA IXIENA            | A, H            |   |
| 2872  | KRAMERIA LAPPACEA          | A, H            |   |
| 2873  | KUNZEA AMBIGUA             | A               | Only for use when the plant preparation is essential oil.<br>Only for use when the route of administration is topical or inhalation.<br>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:<br>- (CHILD) 'Keep out of reach |

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|   |                        |                 | <p>of children'</p> <p>- (EXTERN) 'For external use only'</p> <p>- (UNDILU) 'Not to be applied undiluted to the skin except on the advice of a health care practitioner'.</p> <p>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:</p> <p>- (CHILD) 'Keep out of reach of children'</p> <p>- (EXTERN) 'For external use only'.</p> |
| 2874  | L-BORNEOL              | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>  |
| 2875  | L-BORNYL ACETATE       | E               | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>  |
| 2876  | L-CARVONE              | E               | <p>Permitted for use only in combination with other permitted ingredients as a</p>   |

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|   |                        |                 | flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.   |
| 2877  | L-LIMONENE             | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.                |
| 2878  | L-LINALOOL             | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 2879  | L-MENTHONE             | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2880  | L-MENTHYL ACETATE      | E               | Permitted for use only in combination with other   |

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| <b>Item</b>                                     | <b>Ingredient name</b>           | <b>Purpose</b>  | <b>Specific requirements</b>   |
|   |                                  |                 | permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 2881  | L-ROSE OXIDE                     | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2882  | LABDANUM ABSOLUTE                | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 2883  | LABDANUM GUM EXTRACT ETHYL ESTER | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance and the total fragrance concentration in a medicine is no more than 1%.   |
| 2884  | LABDANUM OIL                     | A, E, H         |  |
| 2885  | LABURNUM ANAGYROIDES             | A, H            | Sparteine is a mandatory component of Laburnum anagyroides.  |

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|   |                        |                 | The concentration of sparteine in the medicine must be no more than 0.001%.  |
| 2886  | LACTALBUMIN            | E               |  |
| 2887  | 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.<br><br>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. |
| 2888  | LACTITOL               | E               | The medicine requires the following warning statements on the medicine label:<br>- (SUGOLS) 'Medicines containing lactitol may have a laxative effect or cause diarrhoea' (or words to that effect);<br>- (LACT) 'Contains lactose' (or words to that effect); and<br>- (COWMK) 'Derived from cows milk'.  |
| 2889  | LACTITOL MONOHYDRATE   | E               | The medicine requires the following warning statements on the medicine label:<br>- (SUGOLS) 'Medicines containing lactitol monohydrate may have a laxative effect or cause   |

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|   |   |                 | diarrhoea' (or words to that effect)<br>- (LACT) 'Contains lactose' (or words to that effect)<br>- (COWMK) 'Derived from cows milk'. |
| 2890  | LACTOBACILLUS ACIDOPHILUS                   | A               |  |
| 2891  | LACTOBACILLUS<br>AMYLOVORUS                 | A               |  |
| 2892  | LACTOBACILLUS BREVIS                        | A               |  |
| 2893  | LACTOBACILLUS CASEI                         | A               |  |
| 2894  | LACTOBACILLUS CASEI SUBSP.<br>BIOVAR CASEI  | A               |  |
| 2895  | LACTOBACILLUS CRISPATUS                     | A               |  |
| 2896  | LACTOBACILLUS DELBRUECKII<br>SSP BULGARICUS | A               |  |
| 2897  | LACTOBACILLUS DELBRUECKII<br>SSP LACTIS     | A               |  |
| 2898  | LACTOBACILLUS FERMENTUM                     | A               |  |
| 2899  | LACTOBACILLUS<br>GALLINARUM                 | A               |  |
| 2900  | LACTOBACILLUS GASSERI                       | A               |  |
| 2901  | LACTOBACILLUS HELVETICUS                    | A               |  |
| 2902  | LACTOBACILLUS JOHNSONII                     | A               |  |
| 2903  | LACTOBACILLUS<br>KEFIRANOFACIENS            | A               |  |
| 2904  | LACTOBACILLUS<br>KEFIRGRANUM                | A               |  |
| 2905  | LACTOBACILLUS KEFIRI                        | A               |  |
| 2906  | LACTOBACILLUS PARACASEI                     | A               |  |
| 2907  | LACTOBACILLUS PARACASEI<br>SUBSP. PARACASEI | A               |  |
| 2908  | LACTOBACILLUS PLANTARUM                     | A               |  |
| 2909  | LACTOBACILLUS REUTERI                       | A               |  |
| 2910  | LACTOBACILLUS RHAMNOSUS                     | A               |  |
| 2911  | LACTOBACILLUS SALIVARIUS<br>SSP SALICINIUS  | A               |  |
| 2912  | LACTOBACILLUS SALIVARIUS                    | A               |  |



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|   | SSP SALIVARIUS         |                 |   |
| 2913  | LACTOBIONIC ACID       | E               | Only for use in topical medicines for dermal application.   |
| 2914  | LACTOSCATONE           | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 2915  | 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:<br>- (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.<br>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:<br>- (LACT) ‘Contains lactose [or words to that effect]’. |
| 2916  | 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,   |

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|   |                        |                 | and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:<br>- (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.<br>If one of the sugars is lactose monohydrate then the medicine also requires the following warning statement on the medicine label:<br>- (LACT) ‘Contains lactose monohydrate [or words to that effect]’. |
| 2917  | LACTUCA SATIVA         | A, H            |   |
| 2918  | LACTUCA VIROSA         | A, H            |   |
| 2919  | LACTULOSE              | E               |   |
| 2920  | 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.   |
| 2921  | LAGENARIA VULGARIS     | A, H            |   |
| 2922  | LAMINARIA CLOUSTONI    | A, E, H         | Iodine is a mandatory component of Laminaria cloustoni.<br>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is   |

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|   |                        |                 | 2.5% or less.<br>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.  |
| 2923  | LAMINARIA DIGITATA     | A, E, H         | Iodine is a mandatory component of Laminaria digitata.<br>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.<br>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 2924  | LAMINARIA JAPONICA     | A, E, H         | Iodine is a mandatory component of Laminaria japonica.<br>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.<br>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 2925  | LAMIUM ALBUM           | A, H            |   |
| 2926  | LANETH-5               | E               | Only for use in topical medicines for dermal application.   |

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| 2927  | LANOLIN ALCOHOL        | E               | Only for use in topical medicines for dermal application.  |
| 2928  | LANOLIN OIL            | E               | Only for use in topical medicines for dermal application.  |
| 2929  | LANOLIN WAX            | E               | Only for use in topical medicines for dermal application.  |
| 2930  | LANTANA CAMARA         | A, H            | The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.  |
| 2931  | LARIX ARABINOGALACTAN  | A, E            | <p>The concentration of polysaccharides in the ingredient must be greater than or equal to 85%.</p> <p>The ingredient must be derived from Larix occidentalis or Larix laricina.</p> <p>Only for use in oral medicines or topical medicines for dermal application, and not to be included in topical products intended for use in the eye.</p> <p>The maximum recommended daily dose of Larix arabinogalactan in oral medicines must not be more than 15 grams.</p> <p>The concentration of Larix arabinogalactan in topical medicines for dermal application must not exceed 5.0%.</p> |
| 2932  | LARIX DECIDUA          | A, H            |  |
| 2933  | LARIX KAEMPFERI        | A, H            | The maximum recommended  |

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|   |                        |                 | daily dose must be no more than 1 mg of the equivalent dry herbal material of Larix kaempferi.  |
| 2934  | LARREA TRIDENTATA      | A, H            | The medicine requires the following warning statement on the medicine label:<br>- (CHAP) 'WARNING: Chaparral may harm the liver in some people - use only under supervision of a health care professional'.   |
| 2935  | LATHYRUS SATIVUS       | A, H            | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lathyrus sativus.<br>The medicine must not contain lathyrogenic amino acids.   |
| 2936  | LAURAMINE OXIDE        | E               |   |
| 2937  | LAUREL LEAF OIL        | A, H            |   |
| 2938  | LAURETH-10             | E               | Only for use in topical medicines for dermal application.   |
| 2939  | LAURETH-12             | E               | Only for use in topical medicines for dermal application.   |
| 2940  | 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.<br>The concentration in the medicine must be no more than 0.4%.<br>Residual levels of ethylene oxide (and related substances) must be kept below the level of |

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|   |                                   |                 | detection.   |
| 2941  | LAURETH-23                        | E               | Only for use in topical medicines for dermal application.  |
| 2942  | LAURETH-3                         | E               | Only for use in topical medicines for dermal application.  |
| 2943  | LAURETH-4                         | E               | Only for use in topical medicines for dermal application.  |
| 2944  | LAURETH-7                         | E               | Only for use in topical medicines for dermal application.  |
| 2945  | LAURETH-8                         | E               |  |
| 2946  | 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.   |
| 2947  | LAURIL MACROGOL 400<br>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.<br>The concentration in the medicine must be no more than 5%. |
| 2948  | LAUROMACROGOL 400                 | E               | Only for use in topical medicines for dermal application.  |
| 2949  | LAUROYL LYSINE                    | E               | Only for use in topical medicines for dermal application and not to be included in medicines for use   |

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|   |                        |                 | in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 5.0%.   |
| 2950  | LAURUS NOBILIS         | A, E, H         | <p>When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 25 millilitres.</p> <p>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.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> |
| 2951  | LAURYL ALDEHYDE        | E               | Permitted for use only in combination with other permitted ingredients as a coating solution, flavour or a fragrance.  |

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|   |                        |                 | <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>  |
| 2952  | LAURYL BETAINE         | E               | Only for use in topical medicines for dermal application.   |
| 2953  | LAURYL GLUCOSIDE       | E               | <p>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.</p> <p>The concentration in the medicine must be no more than 12%.</p>  |
| 2954  | LAURYL LACTATE         | E               | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p> <p>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.</p> |
| 2955  | LAURYL PCA             | E               | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the</p>  |



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| <b>Item</b>                                     | <b>Ingredient name</b>  | <b>Purpose</b>  | <b>Specific requirements</b>   |
|   |   |                 | medicine must be no more than 1%.  |
| 2956  | LAURYL PEG-10<br>TRIS(TRIMETHYLSILOXY)SILYL<br>ETHYL DIMETICONE | E               | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br><br>The concentration in the medicine must be no more than 2%.   |
| 2957  | LAURYL PEG-9<br>POLYDIMETHYLSILOXYETHYL<br>DIMETICONE           | E               | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must be no more than 3.5%.   |
| 2958  | LAURYL PEG/PPG-18/18<br>METHICONE                               | E               | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br><br>The concentration in the medicine must be no more than 9%.<br><br>Residual levels of ethylene oxide (and related substances) must be kept below the level of detection. |
| 2959  | 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.<br><br>The concentration must not exceed 1% in leave-on medicines and 3% in wash-  |

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|   |  |                 | on/wash-off medicines.   |
| 2960  | LAURYL PYRROLIDONE                                   | E               | Only for use in topical medicines for dermal application.  |
| 2961  | LAURYL DIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN    | E               | Only for use in topical medicines for dermal application.  |
| 2962  | LAURYL DIMONIUM 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.<br>The concentration in the medicine must be no more than 0.007%.  |
| 2963  | LAURYL METICONE COPOLYOL                             | E               | Only for use in topical medicines for dermal application.  |
| 2964  | LAVANDIN OIL   | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2965  | LAVANDIN OIL ABRIAL                                  | A, E, H         |  |
| 2966  | LAVANDIN OIL GROSSO                                  | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than  |

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|   |   |                 | 1%.   |
| 2967  | LAVANDULA ANGUSTIFOLIA                        | A, E, H         | Camphor is a mandatory component of Lavandula angustifolia.<br>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.<br>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.                     |
| 2968  | LAVANDULA ANGUSTIFOLIA<br>SUBSP. ANGUSTIFOLIA | A, E, H         | Camphor is a mandatory component of Lavandula angustifolia subsp. angustifolia.<br>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.<br>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. |
| 2969  | LAVANDULA X INTERMEDIA                        | A, E, H         | Camphor is a mandatory component of Lavandula x intermedia.<br>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.   |
| 2970  | LAVENDER OIL                                  | A, E, H         |   |
| 2971  | LAWSONIA INERMIS                              | A, H            |   |
| 2972  | LEAD  | H               | Only for use as an active homoeopathic ingredient.<br>The concentration in the medicine must be no more than 0.001%.  |

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| 2973  | LEAD ACETATE             | H               | Only for use as an active homoeopathic ingredient.  |
| 2974  | LEAF ACETAL              | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 2975  | LECITHIN                 | A, E            |   |
| 2976  | LEDEBOURIELLA SESELOIDES | A, H            |   |
| 2977  | LEDUM GROENLANDICUM      | A, H            |   |
| 2978  | LEDUM PALUSTRE           | A, H            | Beta-arbutin is a mandatory component of <i>Ledum palustre</i> .<br><br>When for dermal application exclusively to the face:<br>a) the concentration of beta-arbutin in the medicine must not be more than 7%;<br>b) hydroquinone is a mandatory component; and<br>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.<br><br>When for topical use other than dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.<br><br>When the route of administration is other than topical, the maximum recommended daily dose must not contain more than 0.001 mg of the equivalent dry herbal material of <i>Ledum palustre</i> . |

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| 2979  | LEMNA MINOR            | A, H            |  |
| 2980  | LEMON                  | E               | When used internally, oxedrine is a mandatory component of lemon.<br><br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.  |
| 2981  | LEMON BALM LEAF DRY    | A, H            |  |
| 2982  | LEMON BALM LEAF POWDER | A, E, H         |  |
| 2983  | LEMON OIL              | A, E, H         | When used internally, oxedrine is a mandatory component of lemon oil.<br><br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.<br><br>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:<br>a) steam distilled or rectified;<br>or<br>b) for internal use; or<br>c) contains 0.05% or less of lemon oil; or<br>d) for use in soaps or bath or shower gels that are washed off the skin. |
| 2984  | LEMON OIL DISTILLED    | A, E, H         | When used internally, oxedrine is a mandatory component of lemon oil distilled.<br><br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.  |
| 2985  | LEMON OIL TERPENELESS  | A, E, H         | When used internally, oxedrine is a mandatory component of   |

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|   |                                   |                 | lemon oil terpeneless.<br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.   |
| 2986  | LEMON OIL TERPENES AND TERPENOIDS | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2987  | LEMON PEEL DRIED                  | A, E, H         | When used internally, oxedrine is a mandatory component of lemon peel dried.<br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.   |
| 2988  | LEMONGRASS OIL                    | A, E, H         |  |
| 2989  | LENS CULINARIS                    | A, H            |  |
| 2990  | LENTIL                            | E               |  |
| 2991  | LENTINULA EDODES                  | A, E, H         |  |
| 2992  | 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.<br>The concentration in the medicine must be no more than 1%.  |
| 2993  | LEONURUS CARDIACA                 | A, E, H         |  |
| 2994  | LEONURUS SIBIRICUS                | A, E, H         |  |
| 2995  | LEPIDIUM APETALUM                 | A, H            |  |

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| 2996  | LEPIDIUM MEYENII           | A               | <p>Only for use in oral medicines when the plant part is tuber and the plant preparation is dry.</p> <p>The maximum recommended daily dose must be no more than 3.5g of <i>Lepidium meyenii</i> dried tuber (or its extract equivalent).</p>  |
| 2997  | LEPTOSPERMUM PETERSONII    | E               | <p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more 5%.</p>   |
| 2998  | LEPTOSPERMUM SCOPARIUM OIL | A               | <p>Only for use as an active ingredient when the route of administration is topical or oral application in a mouthwash preparation.</p> <p>If the concentration is more than 25%, the nominal capacity of the container must be no more than 25mL.</p> <p>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:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or word to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul> <p>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</p> |

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|   |                                 |                 | container and requires the following warning statements on the medicine label:<br>- (CHILD) 'Keep out of reach of children' (or word to that effect)<br>- (NTAKEN) 'Not to be taken'  |
| 2999  | LESPEDEZA CAPITATA              | A, H            |   |
| 3000  | LETTUCE                         | E               |   |
| 3001  | LEUCINE                         | A, E            |   |
| 3002  | LEUZEA UNIFLORUM                | A, H            |   |
| 3003  | LEVISTICUM OFFICINALE           | A, H            |   |
| 3004  | LEVOCARNITINE                   | A               |   |
| 3005  | LEVOCARNITINE FUMARATE          | A               |   |
| 3006  | LEVOCARNITINE HYDROCHLORIDE     | A               |   |
| 3007  | LEVOCARNITINE MAGNESIUM CITRATE | A               |   |
| 3008  | LEVOCARNITINE TARTRATE          | A               |   |
| 3009  | LEVOMEFOLATE CALCIUM            | A               | Available for medicines intended for internal use only.<br>Levomefolic acid is a mandatory component of Levomefolate calcium.<br>The maximum recommended daily dose must not provide more than 500 micrograms of Levomefolic acid from Levomefolate calcium.<br>When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.<br>When used in preparations indicated for reducing the risk of having a child with spina |



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|   |                             |                 | bifida/neural tube defects the following warning statement is required on the medicine label:<br>- (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)'.   |
| 3010  | LEVOMEFOLATE<br>GLUCOSAMINE | A               | Available for medicines intended for internal use only.<br>Levomefolic acid is a mandatory component of levomefolate glucosamine.<br>The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate glucosamine.<br>When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.<br>When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects the following warning statement is required on the medicine label:<br>- (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).' |
| 3011  | LEVOTHYROXINE SODIUM        | H               | Only for use as an active  |

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|   |                        |                 | homeopathic ingredient.   |
| 3012  | LEVULINIC ACID         | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3013  | LIGHT KAOLIN           | E               |   |
| 3014  | 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.                     |
| 3015  | LIGHT MAGNESIUM OXIDE  | A, E, H         |   |
| 3016  | LIGUSTICUM SINENSE     | A, H            |   |
| 3017  | LIGUSTICUM STRIATUM    | A, E, H         |   |
| 3018  | LIGUSTRUM LUCIDUM      | A, H            |   |
| 3019  | LILIUM BROWNII         | A, H            |   |
| 3020  | LILIUM CANDIDUM        | A, E, H         |   |
| 3021  | LILIUM LANCIFOLIUM     | A, H            |   |
| 3022  | LILIUM LONGIFLORUM     | A, H            |   |
| 3023  | LIME FRUIT             | E               |   |
| 3024  | LIME OIL               | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br><br>If used in a fragrance the total fragrance concentration in a |

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| <b>Item</b>                                     | <b>Ingredient name</b>           | <b>Purpose</b>  | <b>Specific requirements</b>  |
|   |                                  |                 | medicine must be no more 1%.  |
| 3025  | 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:<br>a) for internal use; or<br>b) contains 0.5% or less of lime oil coldpressed; or<br>c) for use in soaps or bath or shower gels that are washed off the skin. |
| 3026  | LIME OIL DISTILLED               | A, E, H         | The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:<br>a) for internal use; or<br>b) contains 0.5% or less of lime oil distilled; or<br>c) for use in soaps or bath or shower gels that are washed off the skin.   |
| 3027  | LIME OIL TERPENELESS             | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3028  | LIME OIL TERPENES AND TERPENOIDS | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a  |

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| <b>Item</b>                                     | <b>Ingredient name</b>  | <b>Purpose</b>  | <b>Specific requirements</b>   |
|   |                         |                 | medicine must be no more than 5%.  |
|   |                         |                 | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.   |
| 3029  | LIME TREE FLOWER DRY    | A, H            |  |
| 3030  | LIME TREE FLOWER POWDER | A, H            |  |
| 3031  | LIME, ESSENCE           | E               |  |
| 3032  | LIMES TERPENES          | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3033  | LIMONENE                | E               | When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.   |
| 3034  | LINALOOL                | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3035  | LINALOOL OXIDE          | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |

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|   |                        |                 | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.   |
| 3036  | LINALYL ACETAL         | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.                                       |
| 3037  | LINALYL ACETATE        | E               | Permitted for use only:<br>(a) in topical medicines for dermal application; and<br>(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.<br>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. |
| 3038  | LINALYL BENZOATE       | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3039  | LINALYL BUTYRATE       | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.   |

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|   |                        |                 | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3040  | LINALYL CINNAMATE      | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3041  | LINALYL FORMATE        | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3042  | LINALYL ISOBUTYRATE    | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3043  | LINALYL PROPIONATE     | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a   |

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|   |  |                 | medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3044  | LINDERA STRYCHNIFOLIA                            | A, H            |  |
| 3045  | 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.<br>The concentration in the medicine must be no more than 0.5%.  |
| 3046  | LINOLEIC ACID                                    | E               |  |
| 3047  | LINOLENIC ACID                                   | E               |  |
| 3048  | LINSEED DRY                                      | A, E, H         |  |
| 3049  | LINSEED OIL                                      | A, E, H         |  |
| 3050  | LINSEED POWDER                                   | A, E, H         |  |
| 3051  | LINUM USITATISSIMUM                              | A, E, H         |  |
| 3052  | LIPASE   | A               | Lipase must only be derived from <i>Rhizopus oryzae</i> and must comply with the relevant compositional guideline<br>When used in an undivided preparation, the unit 'Thousand lipase units per gram' is permitted.<br>When used in a divided preparation, the unit 'Thousand lipase unit' is permitted. |
| 3053  | LIPPIA DULCIS                                    | A, H            |  |
| 3054  | LIQUID GLUCOSE                                   | E               | When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the   |

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|   |                               |                 | <p>maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (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.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p> |
| 3055  | 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.   |
| 3056  | LIQUIDAMBAR FORMOSANA         | A, H            |   |
| 3057  | LIQUIDAMBAR ORIENTALIS        | A, H            |   |
| 3058  | LIQUIDAMBAR STYRACIFLUA       | A, E, H         |   |
| 3059  | LIQUIDAMBAR STYRACIFLUA RESIN | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3060  | LIQUIDAMBAR TAIWANIANA        | A, H            |   |
| 3061  | LIQUORICE                     | E               | Permitted for use only in combination with other  |



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|   |                          |                 | permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3062  | LIQUORICE DRY            | A, E, H         |  |
| 3063  | LIQUORICE LIQUID EXTRACT | A, E, H         |  |
| 3064  | LIQUORICE POWDER         | A, E, H         |  |
| 3065  | LITCHI CHINENSIS         | A, H            |  |
| 3066  | LITHIUM CARBONATE        | H               | Only for use as an active homoeopathic ingredient.   |
| 3067  | LITHOSPERMUM OFFICINALE  | A, H            | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.  |
| 3068  | LITSEA CUBEBA            | A, E, H         |  |
| 3069  | LITSEA CUBEBA OIL        | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3070  | LOBARIA PULMONARIA       | A, H            |  |
| 3071  | 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.  |
| 3072  | LOBELIA INFLATA          | A, H            | The concentration in the medicine must be no more than   |

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|   |                        |                 | 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.  |
| 3073  | 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.   |
| 3074  | LOLIUM PERENNE         | A, H            |   |
| 3075  | LOLIUM TEMULENTUM      | A, H            |   |
| 3076  | LONGIFOLENE            | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br><br>If used in a fragrance the total longifolene concentration in a medicine must be no more than 1%. |
| 3077  | LONICERA CAPRIFOLIUM   | A, E, H         |   |
| 3078  | LONICERA JAPONICA      | A, E, H         |   |
| 3079  | LONICERA PERICLYMENUM  | A, H            |   |
| 3080  | LOPHATHERUM GRACILE    | A, H            |   |
| 3081  | LOQUAT                 | E               |   |
| 3082  | LORANTHUS PARASITICUS  | A, H            |   |
| 3083  | LOROPETALUM CHINENSIS  | A, H            |   |
| 3084  | LOTUS CORNICULATUS     | A, H            |   |
| 3085  | LOVAGE OIL             | A, E, H         |   |
| 3086  | LOVAGE ROOT DRY        | A, H            |   |
| 3087  | LOVAGE ROOT POWDER     | A, H            |   |
| 3088  | LUDWIGIA PROSTRATA     | A, H            |   |
| 3089  | LUFFA CYLINDRICA       | A, H            |   |
| 3090  | LUFFA PURGANS          | A, H            |   |
| 3091  | LUTEIN                 | A, E, H         | When used as an excipient, permitted for use only as a colour in medicines limited to topical and oral routes of administration.  |

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| 3092  | LYCHEE                  | E               |  |
| 3093  | LYCIUM BARBARUM         | A, H            |  |
| 3094  | LYCIUM CHINENSE         | A, E, H         |  |
| 3095  | LYCOPENE                | A, E            |  |
| 3096  | LYCOPERSICON ESCULENTUM | A, E, H         | <p>Steroidal alkaloids calculated as solanine is a mandatory component of Lycopersicon esculentum.</p> <p>The maximum daily dose must not provide more than 10 mg of steroidal alkaloids calculated as solanine.</p> |
| 3097  | LYCOPODIUM ANNOTINUM    | A, H            |  |
| 3098  | LYCOPODIUM CLAVATUM     | A, H            |  |
| 3099  | LYCOPODIUM COMPLANATUM  | A, H            |  |
| 3100  | LYCOPUS EUROPAEUS       | A, H            |  |
| 3101  | LYCOPUS LUCIDUS         | A, H            |  |
| 3102  | LYCOPUS VIRGINICUS      | A, H            | <p>Pulegone is a mandatory component of Lycopus virginicus.</p> <p>The concentration of pulegone in the medicine must be no more than 4%.</p>  |
| 3103  | LYGODIUM JAPONICUM      | A, H            |  |
| 3104  | LYSIMACHIA CHRISTINAE   | A, H            |  |
| 3105  | LYSIMACHIA VULGARIS     | A, H            |  |
| 3106  | LYSINE                  | A, E            |  |
| 3107  | LYSINE HYDROCHLORIDE    | A, E            |  |
| 3108  | LYTHRUM HYSSOPIFOLIA    | A, H            |  |
| 3109  | LYTHRUM SALICARIA       | A, H            |  |
| 3110  | LYTHRUM VERTICILLATUM   | A, H            |  |
| 3111  | MACADAMIA INTEGRIFOLIA  | A, E            |  |
| 3112  | MACADAMIA NUT           | E               |  |
| 3113  | MACADAMIA NUT OIL       | E               |  |
| 3114  | MACADAMIA TERNIFOLIA    | A, E, H         |  |

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| 3115  | MACE                   | E               | <p>Safrole is a mandatory component of Mace.</p> <p>When used internally, the concentration of safrole in the medicine must be no more than 0.1%.</p> <p>When used topically, the concentration of safrole in the medicine must be no more than 1.0%.</p>   |
| 3116  | MACE OIL               | A, H            | <p>Safrole is a mandatory component of Mace oil.</p> <p>When used internally, the concentration of safrole in the medicine must be no more than 0.1%.</p> <p>When used topically, the concentration of safrole in the medicine must be no more than 1.0%.</p> <p>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.</p> |
| 3117  | MACROCYSTIS PYRIFERA   | A, E, H         | <p>Iodine is a mandatory component of <i>Macrocystis pyrifera</i>.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>   |

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| 3118  | MACROGOL 1000            | E               |   |
| 3119  | MACROGOL 1450            | E               | Only for use in topical medicines for dermal application.   |
| 3120  | MACROGOL 1500            | E               |   |
| 3121  | 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.<br>The concentration in the medicine must be no more than 2%.  |
| 3122  | MACROGOL 200             | E               | Only for use in topical medicines for dermal application.   |
| 3123  | MACROGOL 20000           | E               |   |
| 3124  | MACROGOL 300             | E               |   |
| 3125  | MACROGOL 3000            | E               |   |
| 3126  | 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. |
| 3127  | MACROGOL 40              | E               | Only for use in topical medicines for dermal application.   |
| 3128  | MACROGOL 400             | E               |   |
| 3129  | MACROGOL 4000            | E               |   |
| 3130  | MACROGOL 45000           | E               | Only for use in topical medicines for dermal  |

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| 3131  | MACROGOL 600                                 | E               |  |
| 3132  | MACROGOL 6000                                | E               |  |
| 3133  | MACROGOL 600000                              | E               |  |
| 3134  | MACROGOL 800                                 | E               |  |
| 3135  | MACROGOL 8000                                | E               |  |
| 3136  | 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.<br>The concentration in the medicine must be no more than 0.95%. |
| 3137  | MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER | E               | Only for use in oral medicines.<br>The concentration in the medicine must be no more than 5%.  |
| 3138  | MACROPIPER EXCELSUM VAR EXCELSUM             | A, H            |  |
| 3139  | MAGNESIUM AMINO ACID CHELATE                 | A, E, H         | Only for use in oral medicines.<br>The concentration of Magnesium must be no more than 25% of the magnesium amino acid chelate.  |
| 3140  | MAGNESIUM ASCORBATE                          | A, E, H         |  |
| 3141  | MAGNESIUM ASCORBATE MONOHYDRATE              | A, E, H         |  |
| 3142  | MAGNESIUM ASCORBYL PHOSPHATE                 | E               | Only for use in topical medicines for dermal application.  |
| 3143  | MAGNESIUM ASPARTATE                          | A, E, H         |  |
| 3144  | MAGNESIUM ASPARTATE DIHYDRATE                | A, E, H         |  |

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| 3145  | MAGNESIUM ASPARTATE<br>TETRAHYDRATE   | A, E, H         |  |
| 3146  | MAGNESIUM CARBONATE<br>HYDRATE        | A, E, H         |  |
| 3147  | MAGNESIUM CHLORIDE 4.5-<br>HYDRATE    | A               |  |
| 3148  | MAGNESIUM CHLORIDE<br>HEXAHYDRATE     | A, E, H         |  |
| 3149  | MAGNESIUM CITRATE                     | A, E, H         |  |
| 3150  | MAGNESIUM CITRATE<br>NONAHYDRATE      | A, E, H         |  |
| 3151  | MAGNESIUM CITRATE<br>TETRADECAHYDRATE | A, E, H         |  |
| 3152  | MAGNESIUM DIGLUTAMATE                 | A, E, H         |  |
| 3153  | MAGNESIUM GLUCONATE                   | A, E, H         |  |
| 3154  | MAGNESIUM<br>GLYCEROPHOSPHATE         | A, E, H         |  |
| 3155  | MAGNESIUM GLYCINATE                   | A               | Only for use in oral medicines.  |
| 3156  | MAGNESIUM GLYCINATE<br>DIHYDRATE      | A               | Only for use in oral medicines.<br>Magnesium is a mandatory<br>component of Magnesium<br>glycinate dihydrate.<br>The percentage of Magnesium<br>from Magnesium glycinate<br>dihydrate should be calculated<br>based on the molecular weight<br>of Magnesium glycinate<br>dihydrate.  |
| 3157  | MAGNESIUM HYDROGEN<br>PHOSPHATE       | H               |  |
| 3158  | MAGNESIUM HYDROXIDE                   | A, E            | When used as an active<br>ingredient, can only be<br>supplied as an un-compounded<br>medicine substance packed for<br>retail sale, and must comply<br>with an un-compounded<br>substance monograph of the<br>British Pharmacopoeia, as in<br>force or existing from time to<br>time. |

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|   |                                  |                 | When the medicine is not promoted or marketed as laxative, contains more than 2 g magnesium hydroxide per maximum recommended daily dose, the following warning statements are required on the label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'<br>- (LAX4) 'This product may have laxative effect'. |
| 3159  | MAGNESIUM LYSINATE               | A               | Only for use in oral medicines.   |
| 3160  | MAGNESIUM METHIONINATE           | A               | Only for use in oral medicines.   |
| 3161  | MAGNESIUM NITRATE                | E               | Only for use in topical medicines for dermal application.   |
| 3162  | MAGNESIUM OROTATE                | A, E, H         |   |
| 3163  | MAGNESIUM OROTATE DIHYDRATE      | A, E, H         |   |
| 3164  | MAGNESIUM OXIDE                  | A, E, H         |   |
| 3165  | MAGNESIUM PHOSPHATE PENTAHYDRATE | A, E, H         |   |
| 3166  | 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.   |
| 3167  | MAGNESIUM PYRUVATE               | A               | Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.  |



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| 3168  | MAGNESIUM STEARATE                | E               |   |
| 3169  | MAGNESIUM SULFATE<br>DIHYDRATE    | A, E, H         | When used internally, the maximum recommended daily dose must be no more than 1.5g. |
| 3170  | MAGNESIUM SULFATE<br>HEPTAHYDRATE | A, E, H         | When used internally, the maximum recommended daily dose must be no more than 1.5g. |
| 3171  | MAGNESIUM SULFATE<br>MONOHYDRATE  | A, E, H         | When used internally, the maximum recommended daily dose must be no more than 1.5g. |
| 3172  | MAGNESIUM SULFATE<br>TRIHYDRATE   | A, E, H         | When used internally, the maximum recommended daily dose must be no more than 1.5g. |
| 3173  | MAGNESIUM TRISILICATE             | E               |   |
| 3174  | MAGNOLIA GLAUCA                   | A, H            |   |
| 3175  | MAGNOLIA LILIFLORA                | A, H            |   |
| 3176  | MAGNOLIA OBOVATA                  | A, H            |   |
| 3177  | MAGNOLIA OFFICINALIS              | A, E, H         |   |
| 3178  | MAGNOLIA SALICIFOLIA              | A, H            |   |
| 3179  | MAIZE                             | E               |   |
| 3180  | MAIZE BRAN                        | E               |   |
| 3181  | MAIZE OIL                         | A, E, H         |   |
| 3182  | MAIZE STARCH                      | A, E, H         |   |
| 3183  | MALACHITE GREEN                   | E               | Permitted for use only as a colour for topical use.                                 |
| 3184  | MALIC ACID                        | E               | Sponsors should consider the impact of excipients on the sensitivity of the skin to |

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|   |                        |                 | sunlight and should ensure the finished medicine is safe for its intended purpose.   |
| 3185  | MALPIGHIA GLABRA       | A, E, H         |  |
| 3186  | MALT EXTRACT           | E               |  |
| 3187  | 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:<br>- (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]'   |
| 3188  | 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:<br>- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea' (or words to that effect). |
| 3189  | 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.   |

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| 3190  | MALTOL                 | E               |   |
| 3191  | MALTONE                | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3192  | 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:<br><br>- (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.<br><br>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:<br><br>- (LACT) 'Contains lactose' (or words to that effect). |
| 3193  | MALUS DOMESTICA        | A, E, H         | The concentration of amygdalin in the medicine must be no more than 0%.   |
| 3194  | MALUS PUMILA           | A, E, H         | A medicine that contains the ingredient must not be listed in the Register on or after 2 March 2020 or be released for supply after 2 March 2021.   |

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| 3195  | MALUS SYLVESTRIS         | A, H            |  |
| 3196  | MALVA MOSCHATA           | A, H            |  |
| 3197  | MALVA SYLVESTRIS         | A, E, H         |  |
| 3198  | MALVA VERTICILLATA       | A, H            |  |
| 3199  | MANDARIN                 | E               |  |
| 3200  | MANDARIN OIL             | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3201  | MANDARIN OIL COLDPRESSED | A, E, H         | When used internally, oxdrine is a mandatory component of mandarin oil coldpressed.<br>The quantity of oxdrine in the maximum recommended daily dose must be no more than 30 milligrams.   |
| 3202  | MANDARIN OIL TERPENES    | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3203  | MANDARIN RESIDUE         | E               | Permitted for use only in combination with other permitted ingredients as a flavour.   |

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|   |                            |                 | If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3204  | MANDARINAL 32048           | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3205  | MANDRAGORA OFFICINARUM     | A, H            | Atropine, hyoscine and hyoscyamine are mandatory components of Mandragora officinarum.<br>The concentration in the medicine must be no more than 10 mg/kg or 10 mL/L or 0.001%.<br>The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.<br>The concentration of hyoscine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.<br>The concentration of hyoscyamine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%. |
| 3206  | MANGANESE                  | H               | Only for use as an active homoeopathic ingredient.  |
| 3207  | MANGANESE (II) DIASPARTATE | A, H            | Only for use in oral medicines.   |

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| 3208  | MANGANESE (II) GLYCINATE           | A, H            | Only for use in oral medicines.   |
| 3209  | MANGANESE ACETATE<br>TETRAHYDRATE  | H               | Only for use as an active homoeopathic ingredient.  |
| 3210  | MANGANESE AMINO ACID<br>CHELATE    | A, E, H         | Only for use in oral medicines.<br>The concentration of Manganese must be no more than 25% of the manganese amino acid chelate.   |
| 3211  | MANGANESE CHLORIDE<br>TETRAHYDRATE | A, E, H         |   |
| 3212  | MANGANESE DIASPARTATE              | A, E, H         | Only for use in oral medicines.   |
| 3213  | MANGANESE GLUCONATE                | A, E, H         |   |
| 3214  | MANGANESE<br>GLYCEROPHOSPHATE      | A, E, H         |   |
| 3215  | MANGANESE OXIDE                    | A, E, H         |   |
| 3216  | MANGANESE SULFATE<br>MONOHYDRATE   | A, E, H         |   |
| 3217  | MANGANESE SULFATE<br>TETRAHYDRATE  | A, E, H         |   |
| 3218  | MANGIFERA INDICA                   | A, E, H         |   |
| 3219  | MANGO                              | E, H            |   |
| 3220  | MANIHOT ESCULENTA                  | A, H            |   |
| 3221  | 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:<br>- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a |

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|   |                         |                 | laxative effect or cause diarrhoea' (or words to that effect).  |
| 3222  | MARANTA ARUNDINACEA     | A, H            |   |
| 3223  | MARINE SPONGE           | H               | Only for use as an active homoeopathic ingredient.  |
| 3224  | 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:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect). |
| 3225  | 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:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect). |
| 3226  | MARRUBIUM VULGARE       | A, E, H         |   |
| 3227  | MARSDENIA CUNDURANGO    | A, H            |   |
| 3228  | MARSHMALLOW ROOT DRY    | A, H            |   |
| 3229  | MARSHMALLOW ROOT POWDER | A, H            |   |
| 3230  | MASSOIA LACTONE         | E               | Permitted for use only in combination with other permitted ingredients as a flavour.  |

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|   |                        |                 | If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3231  | MASTIC                 | A, H            |   |
| 3232  | MATE ABSOLUTE          | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3233  | MATRICARIA CHAMOMILLA  | A, E, H         |   |
| 3234  | MATRICARIA FLOWER DRY  | A, E, H         |   |
| 3235  | MEADOWSWEET HERB DRY   | A, H            | Methyl salicylate is a mandatory component of meadowsweet herb dry.<br>Not to be included in medicines for use in the eye or on damaged skin.<br>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.<br>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.<br>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:<br>- the delivery device is engaged |



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|   |                        |                 | <p>into the container in such a way that prevents it from being readily removed;</p> <ul style="list-style-type: none"> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</li> </ul> <p>When for use in topical medicines for dermal application</p> <ul style="list-style-type: none"> <li>i) the concentration of methyl salicylate in the medicine must not be more than 25%</li> <li>ii) the following warning statements are required on the medicine label:                             <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</li> </ul> </li> <li>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the</li> </ul> |

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|   |                                  |                 | medicine label:<br>- (IRRIT) 'If irritation develops, discontinue use'.  |
| 3236  | MECOBALAMIN (CO-METHYLCOBALAMIN) | A               | Only for use in oral medicines.  |
| 3237  | MEDICAGO SATIVA                  | A, E, H         | The level of l-canavanine must be no more than that of the dried leaf.<br><br>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.   |
| 3238  | MEDIUM CHAIN TRIGLYCERIDES       | E               |  |
| 3239  | MELALEUCA ALTERNIFOLIA           | A, E, H         | Cineole is a mandatory component of Melaleuca alternifolia.<br><br>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:<br><br>a) the nominal capacity of the container must be no more than 25 millilitres;<br><br>b) a restricted flow insert must be fitted on the container; and<br><br>c) the container must include the following warning statements on the medicine label:<br><br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br><br>- (NTAKEN) 'Not to be taken'.<br><br>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the |

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| 3240  | MELALEUCA CAJUPUTI     | A, E, H         | <p>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.</p> <p>Cineole is a mandatory component of Melaleuca cajuputi.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>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.</p> |
| 3241  | MELALEUCA CITRINA      | A, H            |   |
| 3242  | MELALEUCA DISSITIFLORA | A, H            | Cineole is a mandatory component of Melaleuca   |

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|   |                        |                 | <p>dissitiflora.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>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.</p> |
| 3243  | MELALEUCA ERICIFOLIA   | A, E, H         | <p>Cineole is a mandatory component of Melaleuca ericifolia.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include</p>   |

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|   |                        |                 | <p>the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>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.</p>  |
| 3244  | MELALEUCA LINARIIFOLIA | A, H            | <p>Cineole is a mandatory component of Melaleuca linariifolia.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none"> <li>a) the nominal capacity of the container must be no more than 25 millilitres;</li> <li>b) a restricted flow insert must be fitted on the container; and</li> <li>c) the container must include the following warning statements on the medicine label:</li> </ul> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the</p> |

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|   |                         |                 | nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.  |
| 3245  | MELALEUCA OIL           | A, E, H         | <p>Cineole and cajuput oil are a mandatory components of Melaleuca Oil.</p> <p>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:</p> <ul style="list-style-type: none"> <li>- (CHILD) ‘Keep out of reach of children’ (or word to that effect)</li> <li>- (NTAKEN) ‘Not to be taken’.</li> </ul> <p>When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container.</p> <p>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.</p> |
| 3246  | MELALEUCA QUINQUENERVIA | A, E, H         | <p>Cineole is a mandatory component of Melaleuca quinquenervia.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none"> <li>a) the nominal capacity of the container must be no more than</li> </ul>  |

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|   |                            |                 | <p>25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>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.</p> |
| 3247  | MELICOPE PTELEIFOLIA       | A, H            |   |
| 3248  | MELILOTUS OFFICINALIS      | A, E, H         | <p>Coumarin is a mandatory component of Melilotus officinalis.</p> <p>The concentration of coumarin in the medicine must be no more than 0.001%.</p>  |
| 3249  | MELISSA OFFICINALIS        | A, E, H         |   |
| 3250  | MELON                      | E               |   |
| 3251  | MENADIONE SODIUM BISULFITE | E               |   |
| 3252  | MENAQUINONE 7              | A               | <p>For oral use only.</p> <p>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</p>   |

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|   |                        |                 | daily dose in children less than 10 years of age.  |
| 3253  | MENISPERMUM CANADENSE  | A, H            |  |
| 3254  | MENTHA AQUATICA        | A, H            | <p>Menthol is a mandatory component of <i>Mentha aquatica</i>. When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>- (MENTH) Contains a high concentration of menthol, which can cause severe skin</p> |



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|   |                        |                 | irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.   |
| 3255  | MENTHA ARVENSIS        | A, E, H         | Menthol is a mandatory component of Mentha arvensis.<br>When the medicine is for topical use for dermal application:<br>(i) the medicine must not be intended for use in the eye or on damaged skin;<br>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>(iii) the following warning statement is required on the medicine label:<br>- (EYE) Avoid contact with eyes (or words to that effect).<br>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:<br>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;<br>- (IRRIT) If irritation develops, discontinue use.<br>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: |

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|                 |                          |                 | <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>   |
| 3256            | MENTHA ARVENSIS LEAF OIL | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more 1%.</p> <p>Menthol is a mandatory component of Mentha arvensis leaf oil.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol</p> |

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|   |                        |                 | <p>when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</li> <li>- (IRRIT) If irritation develops, discontinue use.</li> </ul> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</li> </ul> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p> |
| 3257  | MENTHA ARVENSIS OIL    | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must not be more than 5%.</p> <p>Menthol is a mandatory component of Mentha arvensis oil.</p> <p>When the medicine is for topical use for dermal application:</p> <ul style="list-style-type: none"> <li>(i) the medicine must not be intended for use in the eye or on damaged skin;</li> </ul>   |

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|   |                        |                 | <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statements is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (EYE) Avoid contact with eyes (or words to that effect).</li> </ul> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</li> <li>- (IRRIT) If irritation develops, discontinue use.</li> </ul> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</li> </ul> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p> |
| 3258  | MENTHA HAPLOCALYX      | A, E, H         | <p>Menthol is a mandatory component of Mentha haplocalyx.</p> <p>When the medicine is for topical use for dermal application:</p>   |

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| <b>Item</b>                                     | <b>Ingredient name</b> | <b>Purpose</b>  | <b>Specific requirements</b>  |
|   |                        |                 | <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p> |
| 3259  | MENTHA PULEGIUM        | A, H            | D-pulegone, menthol and volatile oil components (of Mentha pulegium) are  |

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|   |                        |                 | <p>mandatory components of <i>Mentha pulegium</i>.</p> <p>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%.</p> <p>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.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (NTAKEN) 'Not to be taken';</li> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect).</li> </ul> <p>When the medicine is for topical use for dermal application:</p> <ul style="list-style-type: none"> <li>a) the maximum recommended daily dose must not contain more than 150 mg of <i>Mentha pulegium</i> oil or distillate;</li> <li>b) the medicine must not be intended for use in the eye or on damaged skin;</li> <li>c) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</li> <li>d) the following warning statement is required on the medicine label: <ul style="list-style-type: none"> <li>- (EYE) Avoid contact with eyes (or words to that effect).</li> </ul> </li> <li>e) if the medicine delivers more than 1% total menthol when administered according</li> </ul> |

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|   |                        |                 | <p>to the directions for use, the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</li> <li>- (IRRIT) If irritation develops, discontinue use.</li> </ul> <p>f) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</li> </ul> <p>When the medicine is for internal use:</p> <ul style="list-style-type: none"> <li>a) the maximum recommended daily dose must not contain more than 50 mg of Mentha pulegium oil or distillate;</li> <li>b) the maximum recommended daily dose must not contain more than 1 gram of menthol.</li> </ul> |
| 3260  | MENTHA SPICATA         | A, E, H         | <p>Menthol is a mandatory component of Mentha spicata.</p> <p>When the medicine is for topical use for dermal application:</p> <ul style="list-style-type: none"> <li>(i) the medicine must not be intended for use in the eye or on damaged skin;</li> <li>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</li> <li>(iii) the following warning</li> </ul>   |

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| <b>Item</b>                                     | <b>Ingredient name</b> | <b>Purpose</b>  | <b>Specific requirements</b>  |
|   |                        |                 | <p>statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (EYE) Avoid contact with eyes (or words to that effect).</li> <li>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: <ul style="list-style-type: none"> <li>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</li> <li>- (IRRIT) If irritation develops, discontinue use.</li> </ul> </li> <li>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: <ul style="list-style-type: none"> <li>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</li> </ul> </li> </ul> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p> |
| 3261  | MENTHA X CARDIACA      | A, E, H         | <p>Menthol is a mandatory component of Mentha x cardiaca.</p> <p>When the medicine is for topical use for dermal application:</p> <ul style="list-style-type: none"> <li>(i) the medicine must not be intended for use in the eye or on damaged skin;</li> <li>(ii) the medicine must not deliver more than 25% total menthol when administered</li> </ul>  |



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

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|   |                        |                 | <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p> |
| 3263  | MENTHADIENYL ACETATE   | E               | Menthadienyl acetate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.  |

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|   |                        |                 | The total concentration of the flavour proprietary excipient formulation containing menthadienyl acetate must not be more than 5% of the total medicine.  |
| 3264  | MENTHANYL ACETATE      | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3265  | MENTHOFURAN            | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3266  | MENTHOL                | A, E            | When the medicine is for topical use for dermal application:<br>(i) the medicine must not be intended for use in the eye or on damaged skin;<br>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>(iii) the following warning statement is required on the medicine label:<br>- (EYE) Avoid contact with eyes (or words to that effect).<br>(iv) if the medicine delivers more than 1% total menthol when administered according |

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|   |                           |                 | <p>to the directions for use, the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</li> <li>- (IRRIT) If irritation develops, discontinue use.</li> </ul> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</li> </ul> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p> |
| 3267  | MENTHONE                  | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>   |
| 3268  | MENTHONE GLYCERINE ACETAL | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>  |

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| 3269  | MENTHONE THIOL FRACTION           | E               | 5%.<br>Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.                       |
| 3270  | MENTHOXYPROPANEDIOL               | E               | For oral use only.<br>The concentration in the medicine must be no more than 0.04%.  |
| 3271  | MENTHYL 2-HYDROXYETHYL CARBONATE  | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.                              |
| 3272  | MENTHYL 2-HYDROXYPROPYL CARBONATE | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.                              |
| 3273  | 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.<br>The concentration in the medicine must not be more than 5%.<br>When used in primary |

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|   |                            |                 | <p>sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> <li>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</li> </ul> |
| 3274  | MENTHYL ISOVALERATE        | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>   |
| 3275  | MENTHYL LACTATE            | E               |  |
| 3276  | MENYANTHES TRIFOLIATA      | A, H            |  |
| 3277  | MERCURIC CHLORIDE          | H               | Only for use as an active homoeopathic ingredient.   |
| 3278  | MERCURY                    | H               | Only for use as an active homoeopathic ingredient.   |
| 3279  | METACRESOL                 | E               | Only for use in topical medicines for dermal application.  |
| 3280  | METHACRYLIC ACID COPOLYMER | E               | Only for use in oral medicines.  |
| 3281  | METHANOL                   | E               | <p>The residual solvent limit is 30 mg per recommended daily dose.</p> <p>The concentration in the medicine must be no more than 0.3%.</p>   |
| 3282  | METHICONE                  | E               | Only for use in topical  |

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|   |  |                 | medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 1%.  |
| 3283  | METHIONINE   | A, E            |  |
| 3284  | METHYL 2,6,6-TRIMETHYLCYCLOHEX-2-ENE-1-CARBOXYLATE | E               | Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.<br>The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.   |
| 3285  | METHYL 2-METHYLBUTYRATE                            | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3286  | METHYL 2-OCTYNOATE                                 | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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| 3287  | METHYL 3,6-DIMETHYLRESORCYLATE | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3288  | METHYL ACETATE                 | E               | The residual solvent limit is 50 mg per recommended daily dose.<br>The concentration in the medicine must be no more than 0.5%.  |
| 3289  | METHYL ACETOPHENONE            | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3290  | METHYL ACETYLRICINOLEATE       | E               | Only for use in topical medicines for dermal application.  |
| 3291  | METHYL ANISATE                 | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3292  | METHYL ANTHRANILATE            | E               | Permitted for use only in combination with other   |



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|   |                        |                 | permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3293  | METHYL BENZOATE        | E               | Only for use in topical medicines for dermal application.  |
| 3294  | METHYL BUTYRATE        | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3295  | METHYL CAPROATE        | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3296  | METHYL CAPRYLATE       | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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| 3297  | METHYL CARBITOL        | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3298  | METHYL CEDRYL KETONE   | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3299  | METHYL CHAVICOL        | E               | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.<br>The ingredient is not to be included in medicines intended for oral use.<br>The quantity of methyl chavicol in a medicine must be no more than 0.01%.<br>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 3300  | METHYL CINNAMATE       | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a   |

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|   |  |                 | medicine must be no more 1%.   |
| 3301  | METHYL CIS-5-OCTENOATE                           | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3302  | METHYL CYCLOPENTENOLONE                          | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3303  | METHYL<br>CYCLOPENTYLIDENEACETATE                | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3304  | METHYL DI-TERT-BUTYL-4-<br>HYDROXYHYDROCINNAMATE | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3305  | METHYL DIHYDROABIETATE                           | E               | Permitted for use only in combination with other   |

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|   |                                 |                 | permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3306  | METHYL DIISOPROPYL PROPIONAMIDE | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3307  | METHYL ETHER                    | E               | Only for use in topical medicines for dermal application.  |
| 3308  | METHYL ETHYL KETONE             | E               | The residual solvent limit is 50 mg per maximum recommended daily dose.<br>The concentration in the medicine must be no more than 0.5%.  |
| 3309  | METHYL EUGENOL                  | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3310  | METHYL FUROATE                  | E               | Permitted for use only in combination with other permitted ingredients as a flavour.   |

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|   |                                    |                 | If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3311  | 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.<br>The concentration in the medicine must be no more than 3%.<br>Residue levels of ethylene oxide are to be kept below the level of detection. |
| 3312  | METHYL GLUCETH-20                  | E               | Only for use in topical medicines for dermal application.  |
| 3313  | METHYL GLUCETH-20<br>BENZOATE      | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3314  | METHYL GLUCETH-20<br>SESQUIHYDRATE | E               | Only for use in topical medicines for dermal application.  |
| 3315  | METHYL GLUCOSE DIOLEATE            | E               | Only for use in topical medicines for dermal application.  |
| 3316  | METHYL GLUCOSE<br>SESQUIOLEATE     | E               | Only for use in topical medicines for dermal application.  |
| 3317  | METHYL GLUCOSE                     | E               | Only for use in topical  |

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|   | SESQUISTEARATE         |                 | medicines for dermal application.  |
| 3318  | METHYL HEPTANOATE      | E               | Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation.<br><br>The total flavour proprietary excipient formulation in a medicine must not be more than 5%.  |
| 3319  | METHYL HEPTENONE       | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3320  | METHYL HEPTYL KETONE   | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3321  | METHYL HEXYL CARBINOL  | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than  |

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|   |                              |                 | 5%.   |
| 3322  | METHYL HEXYL KETONE          | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3323  | METHYL HYDROGENATED ROSINATE | E               | Only for use in topical medicines for dermal application.   |
| 3324  | METHYL HYDROJASMONATE        | E               | Only for use in topical medicines for dermal application.   |
| 3325  | METHYL HYDROXYBENZOATE       | E               | Medicines containing hydroxybenzoates require the following warning statement on the medicine label:<br>- (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. |
| 3326  | METHYL IONONE                | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than  |

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|   |                        |                 | 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3327  | METHYL ISOBUTYL KETONE | E               | The residual solvent limit is 50 mg per maximum daily dose.<br>The concentration in the medicine must be no more than 0.5%.  |
| 3328  | METHYL ISOEUGENOL      | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3329  | METHYL ISOVALERATE     | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3330  | METHYL JASMONATE       | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3331  | METHYL LAURATE         | E               | Permitted for use only in combination with other   |



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|   |                                  |                 | permitted ingredients as a flavour.<br>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3332  | METHYL LINOLEATE                 | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3333  | METHYL LINOLENATE                | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3334  | METHYL MAGNESIUM CHLORIDE        | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3335  | METHYL METHACRYLATE              | E               |  |
| 3336  | 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.<br>When the concentration of methyl methacrylate crosspolymer is greater than 1%, the medicine must not be |

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|   |                         |                 | intended for use on damaged skin.<br>The concentration in the medicine must not be more than 4.85%.  |
| 3337  | METHYL METHOXY PYRAZINE | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3338  | METHYL MYRISTATE        | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3339  | METHYL NAPHTHYL KETONE  | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3340  | METHYL NONYL KETONE     | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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| 3341  | METHYL NONYLENATE      | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 3342  | METHYL OCTIN CARBONATE | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 3343  | METHYL PALMITATE       | E               | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>  |
| 3344  | METHYL PHENYL CARBINOL | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>  |

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| 3345  | METHYL PHENYL CARBINYL-ISO-BUTYRATE | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3346  | METHYL PHENYL GLYCIDATE             | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3347  | METHYL PHENYLACETATE                | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3348  | METHYL PHENYLCARBINYL ACETATE       | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3349  | METHYL ROSINATE                     | E               | Permitted for use only in combination with other   |

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|   |                        |                 | permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3350  | METHYL SALICYLATE      | A, E            | Not to be included in medicines for use in the eye or on damaged skin.<br>When used internally, the concentration in the medicine must not be more than 0.001%.<br>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.<br>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:<br>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;<br>- direct suction through the delivery device results in delivery of no more than one dosage unit; and<br>- actuation of the spray device is ergonomically difficult for young children to accomplish.<br>The following warning statement is required on the medicine label:<br>- (METSAL) 'Contains methyl salicylate' (or words to that effect).<br>When for use in topical medicines for dermal |

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|   |                        |                 | <p>application:</p> <p>i) the concentration of methyl salicylate in the medicine must not be more than 25%;</p> <p>ii) the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect);</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</li> </ul> <p>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (IRRIT) 'If irritation develops, discontinue use'.</li> </ul> |
| 3351  | METHYL STEARATE        | E               |   |
| 3352  | METHYL THIOBUTYRATE    | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>  |
| 3353  | METHYL TRIMETICONE     | E               | <p>Only for use in topical medicines for dermal application and not to be</p>   |

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|   |                                      |                 | included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%.  |
| 3354  | METHYL-3-METHYLTHIOPROPIONATE        | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.       |
| 3355  | METHYL-BETA-METHYLTHIOLPROPIONATE    | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.       |
| 3356  | METHYL-PARA-TERT-BUTYL PHENYLACETATE | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.       |
| 3357  | METHYLBENZYL ACETATE                 | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3358  | METHYLCELLULOSE                      | A, E            |   |

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| 3359  | METHYLCHLOROISOTHIAZOLI<br>NONE                            | E               | Only for use in topical medicines for dermal application that are rinsed off the skin.<br><br>The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.  |
| 3360  | METHYLCYCLOHEXADIENE                                       | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3361  | METHYLENE BIS-<br>BENZOTRIAZOLYL<br>TETRAMETHYLBUTYLPHENOL | A               | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.<br><br>The concentration in the medicine must not be more than 10%.<br><br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 3362  | METHYLISOTHIAZOLINONE                                      | E               | Only for use in topical medicines for dermal application that are rinsed off the skin.<br><br>The total concentration of  |



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|   |                                      |                 | methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.  |
| 3363  | METHYLMERCAPTAN                      | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.                          |
| 3364  | METHYLPROPANEDIOL                    | E               | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br><br>The concentration in the medicine must be no more than 10%.                     |
| 3365  | 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.<br><br>The concentration in the medicine must be no more than 0.1%. |
| 3366  | METHYLSTYRENE/VINYLTOLUENE COPOLYMER | E               | Only for use in topical medicines for dermal application.  |
| 3367  | MICA                                 | E               | Only for use when the route of administration is oral, dental or topical.<br><br>The concentration in oral medicines must be no more than 2.5%.  |

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|   |                               |                 | The concentration in dental toothpastes must be no more than 0.5%.   |
| 3368  | MICROCALICIUM ARENARIUM       | A, H            |  |
| 3369  | MICROCOCCUS LUTEUS<br>LYSATE  | E               | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br><br>The concentration in the medicine must be no more than 0.005%.  |
| 3370  | MICROCOS PANICULATA           | A, H            |  |
| 3371  | MICROCRYSTALLINE<br>CELLULOSE | E               |  |
| 3372  | MICROCRYSTALLINE WAX          | E               | Only for use as an excipient in medicines for topical, oral or oral application routes of administration.<br><br>When microcrystalline wax is used as an excipient ingredient, the route of administration 'oral' is only permitted when the dosage form is 'chewing gum'. |
| 3373  | MILK FAT                      | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3374  | MILK THISTLE FRUIT DRY        | A, H            |  |
| 3375  | MILK THISTLE FRUIT POWDER     | A, H            |  |
| 3376  | MILLET                        | E               |  |
| 3377  | MILLETTIA DIELSIANA           | A, H            |  |
| 3378  | MIMOSA ABSOLUTE               | E               | Permitted for use only in  |

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|   |                        |                 | <p>combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>   |
| 3379  | MIMULUS GUTTATUS       | A, H            |  |
| 3380  | MINT OIL DEMENTHOLISED | A, E, H         | <p>Menthol is a mandatory component of mint oil dementholised.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according</p> |

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|   |   |                 | to the directions for use, the following warning statement is required on the medicine label:<br>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol. |
| 3381  | MINTLACTONE                                     | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3382  | MITCHELLA REPENS                                | A, H            |   |
| 3383  | MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE | A, E            |   |
| 3384  | MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE  | A, E            |   |
| 3385  | MIXED TERPENES                                  | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3386  | MODIFIED FOOD STARCH                            | E               |   |
| 3387  | MOLASSES  | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than   |

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|   |                              |                 | 5%.   |
| 3388  | MOLYBDENUM                   | H               | Only for use as an active homoeopathic ingredient.<br>When Molybdenum is sourced from Molybdenum trioxide then the maximum daily dose must be no more than 125 micrograms.<br>When Molybdenum is sourced from yeast - high molybdenum then the maximum recommended daily dose must be no more than 62.5 micrograms. |
| 3389  | MOLYBDENUM TRIOXIDE          | A               | Molybdenum is a mandatory component of Molybdenum trioxide.<br>The maximum daily dose of molybdenum from Molybdenum trioxide must be no more than 125 micrograms.<br>The percentage of molybdenum from molybdenum trioxide should be calculated based on the molecular weight of molybdenum trioxide.               |
| 3390  | MOMORDICA BALSAMINA          | A, H            |   |
| 3391  | MOMORDICA CHARANTIA          | A, H            |   |
| 3392  | 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.   |
| 3393  | MONARDA DIDYMA               | A, H            |   |
| 3394  | MONO- AND DI- GLYCERIDES     | E               |   |
| 3395  | MONOBASIC AMMONIUM PHOSPHATE | E               | Only for use in topical medicines for dermal application.   |

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| 3396  | MONOBASIC CALCIUM PHOSPHATE          | A, E, H         |  |
| 3397  | MONOBASIC POTASSIUM PHOSPHATE        | A, E, H         | <p>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.</p> <p>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.</p>   |
| 3398  | MONOBASIC SODIUM PHOSPHATE           | A, E, H         | <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> <p>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:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p> |
| 3399  | MONOBASIC SODIUM PHOSPHATE DIHYDRATE | E               | <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not</p>  |

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|   |                               |                 | <p>exceed 11.5.</p> <p>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:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p> |
| 3400  | MONOETHANOLAMINE              | E               | <p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 5%.</p>  |
| 3401  | MONOMENTHYL SUCCINATE         | E               | <p>Monomethyl succinate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of the flavour proprietary excipient formulation containing monomethyl succinate must not be more than 5% of the total medicine.</p>   |
| 3402  | MONOPHOSPHOTHIAMINE           | A               |   |
| 3403  | MONOPHOSPHOTHIAMINE DIHYDRATE | A               |   |
| 3404  | MONOPOTASSIUM GLUTAMATE       | A, E            |   |
| 3405  | MONOSODIUM DIHYDROGEN CITRATE | E               | <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the</p>   |

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|   |                                  |                 | maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:<br>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’ |
| 3406  | MONOSODIUM GLUTAMATE MONOHYDRATE | A, E            |   |
| 3407  | MONSTERA DELICIOSA               | A, H            |   |
| 3408  | MONTAN WAX                       | E               |   |
| 3409  | MORDANT RED 11                   | E               | Permitted for use only as a colour for topical use.<br>The concentration in the medicine must be no more than 0.05%..   |
| 3410  | MORINDA CITRIFOLIA               | A, H            | Only for use when the plant part is fruit and the plant preparation is fruit juice or fruit powder.<br>Fruit powder must be produced by freeze drying the whole fruit (excluding the seeds).  |
| 3411  | MORINDA OFFICINALIS              | A, H            |   |
| 3412  | MORINGA OLEIFERA                 | A, H            |   |
| 3413  | MORUS ALBA                       | A, H            |   |
| 3414  | MORUS BOMBYCIS                   | A, H            |   |
| 3415  | MORUS NIGRA                      | A, E, H         |   |
| 3416  | MOSKENE                          | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |



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| 3417  | MOTHERWORT HERB DRY    | A, H            |   |
| 3418  | MOTHERWORT HERB POWDER | A, H            |   |
| 3419  | MUCUNA PRURIENS        | A               | Levodopa is a mandatory component of Mucuna pruriens.<br>The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.                               |
| 3420  | MULBERRY               | E               |   |
| 3421  | MUNG BEAN              | E               |   |
| 3422  | MURRAYA KOENIGII       | A, H            |   |
| 3423  | MURRAYA PANICULATA     | A, H            |   |
| 3424  | MUSA X PARADISIACA     | A, H            |   |
| 3425  | MUSK KETONE            | E               | Only for use in topical medicines for dermal application.   |
| 3426  | MUSK TIBETENE          | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3427  | MUSK XYLOL             | E               | Only for use in topical medicines for dermal application.   |
| 3428  | MUSKS                  | H               | Only for use as an active homoeopathic ingredient.  |
| 3429  | MUSTARD                | E               | Allyl isothiocyanate is a mandatory component of mustard when the plant part is seed.<br>The concentration of allyl   |

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|   |                        |                 | isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.   |
| 3430  | MUSTARD OIL            | E               | Allyl isothiocyanate is a mandatory component of mustard oil when the plant part is seed.<br><br>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.   |
| 3431  | MUSTARD SEED OIL       | E               | Allyl isothiocyanate is a mandatory component of mustard seed oil when the plant part is seed.<br><br>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.  |
| 3432  | MYOSOTIS ARVENSIS      | A, H            |  |
| 3433  | MYRCENE                | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3434  | MYRCENYL ACETATE       | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br><br>If used in a fragrance the total fragrance concentration in a  |

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|   |                        |                 | medicine must be no more than 1%.   |
| 3435  | MYRICA CERIFERA        | A, E, H         |   |
| 3436  | MYRISTIC ACID          | E               |   |
| 3437  | MYRISTIC ALDEHYDE      | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3438  | MYRISTICA FRAGRANS     | A, E, H         | Safrole is a mandatory component of Myristica fragrans.<br>When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.<br>When for topical use then the concentration of safrole in the medicine must be no more than 1%.<br>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:<br>- (CHILD) 'Keep out of reach of children' (or word to that effect). |
| 3439  | MYRISTYL ALCOHOL       | E               | Only for use in topical   |

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|   |                                  |                 | medicines for dermal application.  |
| 3440  | MYRISTYL LACTATE                 | E               | Only for use in topical medicines for dermal application.  |
| 3441  | MYRISTYL MYRISTATE               | E               | Only for use in topical medicines for dermal application.  |
| 3442  | MYROXYLON BALSAMUM               | A, E, H         |  |
| 3443  | MYROXYLON BALSAMUM VAR. PEREIRAE | A, H            |  |
| 3444  | MYRRH                            | A, H            |  |
| 3445  | MYRRH OIL                        | A, E, H         |  |
| 3446  | MYRRH RESIN                      | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3447  | MYRRHIS ODORATA                  | A, H            |  |
| 3448  | MYRSINE AFRICANA                 | A, H            |  |
| 3449  | MYRTENAL                         | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3450  | MYRTENYL ACETATE                 | E               | Permitted for use only in combination with other permitted ingredients as a  |

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|   |  |                 | flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3451  | MYRTLE ESSENCE MAX                     | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3452  | MYRTLE OIL                             | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3453  | MYRTUS COMMUNIS                        | A, E, H         |   |
| 3454  | N,N'-BIS(SALICYLIDENE)PROPYLENEDIAMINE | E               | N,N'-Bis(salicylidene)propylenediamine must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application. |
| 3455  | N-BUTYL SULFIDE                        | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than  |

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|   |                         |                 | 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3456  | N-GLUCONYL ETHANOLAMINE | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3457  | N-HEXYL 2-BUTENOATE     | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3458  | N-NONYL ALCOHOL         | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3459  | NAPHTHALENE             | H               | Only for use as an active homoeopathic ingredient.   |
| 3460  | NARDOSTACHYS CHINENSIS  | A, H            |  |
| 3461  | NARINGIN                | E               | Permitted for use only in combination with other permitted ingredients as a  |

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|   |                        |                 | flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3462  | NASTURTIUM OFFICINALE  | A, E, H         |   |
| 3463  | NATURAL FISH OIL       | A, E            | When therapeutic indications for this product are made against Vitamin A or colecalciferol (Vitamin D), they are mandatory components of natural fish oil.<br>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.<br>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.<br>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:<br>- (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use.<br>- (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this |

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|   |                               |                 | warning at the beginning of the directions for use.<br>- (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.'<br>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. |
| 3464  | NAUCLEA OFFICINALIS           | A, H            |   |
| 3465  | NELUMBO NUCIFERA              | A, H            |   |
| 3466  | 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.<br>The concentration in the medicine must be no more than 0.1%.  |
| 3467  | 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.<br>The concentration in the medicine must be no more than 0.1%   |
| 3468  | NEOMENTHOL                    | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |



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| 3469  | NEOPENTYL GLYCOL<br>DIHEPTANOATE            | E               | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 25%.  |
| 3470  | NEOPENTYL GLYCOL<br>DIISOSTEARATE           | E               | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%.   |
| 3471  | NEOPENTYL GLYCOL<br>DIOCTANOATE             | E               | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 8.1%.<br>When the concentration of neopentyl glycol dioctanoate is greater than 5%, the medicine must not be intended for use on damaged skin. |
| 3472  | NEOPENTYL GLYCOL<br>DIOCTANOATE/DIDECANOATE | E               | Only for use in topical medicines for dermal application.   |
| 3473  | NEOPICRORHIZA<br>SCROPHULARIIFLORA          | A, H            |   |
| 3474  | NEPETA CATARIA                              | A, H            | Pulegone is a mandatory component of Nepeta cataria and must be declared in the application.  |

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|   |                        |                 | The concentration of pulegone in the medicine must be no more than 4%.   |
| 3475  | NERAL                  | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3476  | 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%.  |
| 3477  | NEROL                  | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.                               |
| 3478  | NEROL OXIDE            | E               | Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.<br>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.<br>When used in a fragrance, the total fragrance proprietary |

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|   |                        |                 | excipient formulation in a medicine must be no more than 1%.   |
| 3479  | NEROLIDOL              | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3480  | NERONE                 | E               | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.<br>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.   |
| 3481  | NERYL ACETATE          | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3482  | NERYL-ISO-BUTYRATE     | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a  |

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|   |                                |                 | medicine must be no more than 5%.   |
| 3483  | NICKEL                         | H               | Only for use as an active homoeopathic ingredient.  |
| 3484  | NICOTIANA TABACUM              | H               | Only for use as an active homoeopathic ingredient.  |
| 3485  | NICOTINAMIDE                   | A, E, H         |   |
| 3486  | NICOTINAMIDE ASCORBATE         | A, E            |   |
| 3487  | NICOTINAMIDE RIBOSIDE CHLORIDE | A               | <p>Only to be used in a medicine where Chromadex Inc (Client ID 68566), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 02 December 2021.</p> <p>Ribose is a mandatory component of Nicotinamide riboside chloride.</p> <p>Only permitted for use in medicines limited to oral routes of administration.</p> <p>The maximum recommended daily dose of the medicine must not contain more than 300mg of Nicotinamide riboside chloride.</p> <p>The following warning statement is required on the medicine label:</p> <p>- (CHILD3) ‘Not for use in children under the age of 12’.</p> <p>When the maximum recommended daily dose of the medicine provides greater than 230mg of nicotinamide</p> |

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|   |                        |                 | riboside chloride, the following warning statement is required on the medicine label:<br>- (PREG) 'Not recommended for use during pregnancy or lactation'.   |
| 3488  | NICOTINIC ACID         | A, E            | The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.   |
| 3489  | NIGELLA DAMASCENA      | A, H            |  |
| 3490  | NIGELLA SATIVA         | A, E, H         |  |
| 3491  | NITRIC ACID            | E, H            | The concentration of nitric acid in the medicine must be no more than 0.5%.  |
| 3492  | NONADIENOL             | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3493  | NONANAL                | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3494  | NONANOIC ACID          | E               | Permitted for use only in combination with other   |

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|                 |                        |                 | permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.                  |
| 3495            | 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:<br>- (LACT) 'Contains lactose' (or words to that effect).   |
| 3496            | NONIVAMIDE             | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3497            | NONOXINOL 10           | E               | Only for use in topical medicines for dermal application.  |
| 3498            | NONOXINOL 12           | E               | For use in hand scrub formulations for healthcare professionals only.<br>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |

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| 3499  | NONOXINOL 5            | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3500  | NONOXINOL 9            | E               | Only for use in topical medicines for dermal application.<br><br>The concentration in the medicine must be no more than 25%.  |
| 3501  | NONYL ACETATE          | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3502  | NOOTKATONE             | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.       |
| 3503  | NOPYL ACETATE          | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 3504  | 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.<br>The concentration in the medicine must be no more than 0.3%.  |
| 3505  | NOTOPTERYGIUM FORBESII    | A, H            |  |
| 3506  | NOTOPTERYGIUM INCISIUM    | A, H            |  |
| 3507  | NUPHAR JAPONICA           | A, H            |  |
| 3508  | NUPHAR LUTEA              | A, H            |  |
| 3509  | NUTMEG DRY                | A, E, H         | Safrole is a mandatory component of Nutmeg Dry.<br>When for internal use then the concentration of safrole from all ingredients in the medicine must be no more than 0.1%.<br>When for topical use then the concentration of safrole from all ingredients in the medicine must be no more than 1%.   |
| 3510  | NUTMEG OIL                | A, E, H         | Safrole is a mandatory component of Nutmeg oil.<br>When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.<br>When for topical use then the concentration of safrole in the medicine must be no more than 1%.<br>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: |



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|   |                          |                 | - (CHILD) 'Keep out of reach of children' (or words to that effect).   |
| 3511  | NUTMEG POWDER            | A, E, H         | Safrole is a mandatory component of Nutmeg powder.<br>When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.<br>When for topical use then the concentration of safrole in the medicine must be no more than 1%.  |
| 3512  | NUX VOMICA DRY           | A, H            | Strychnine (of Strychnos spp.) is a mandatory component of Nux Vomica Dry.<br>The concentration of in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.  |
| 3513  | NUX VOMICA POWDER        | H               | Only for use as an active homoeopathic ingredient.<br>Strychnine (of Strychnos spp.) is a mandatory component of Nux vomica powder.<br>The concentration in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.  |
| 3514  | NYCTANTHES ARBOR-TRISTIS | A, H            | When the plant part is leaf:<br>a) methyl salicylate is a mandatory component of Nyctanthes arbor-tristis;<br>b) not to be included in medicines for use in the eye or on damaged skin;<br>c) when used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%;<br>d) when the concentration of |

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|   |                        |                 | <p>methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging;</p> <p>e) when the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish;</li> </ul> <p>f) the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that effect); and</li> </ul> <p>g) when for use in topical medicines for dermal application:</p> <ul style="list-style-type: none"> <li>i) the concentration of methyl salicylate in the medicine must not be more than 25%</li> <li>ii) the following warning statements are required on the medicine label:</li> <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or</li> </ul> </ul> |

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|   |                        |                 | less';<br>- (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect);<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);<br>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:<br>- (IRRIT) 'If irritation develops, discontinue use'. |
| 3515  | NYLON                  | E               | Only for use in topical medicines for dermal application.   |
| 3516  | NYLON 6/12             | E               | Only for use in topical medicines for dermal application.   |
| 3517  | NYLON-12               | E               | Only for use in topical medicines for dermal application.   |
| 3518  | NYMPHAEA ALBA          | A, E, H         |   |
| 3519  | 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.<br>The concentration in the medicine to be no more than 0.3%.<br>Only for use in liquid extracts where the plant part is the flower and the solvent in 100% water.  |

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| 3520  | NYMPHAEA ODORATA       | A, H            |  |
| 3521  | OAK CHIPS EXTRACT      | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3522  | OAKMOSS ABSOLUTE       | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3523  | OAT                    | E, H            | Only for use as an active homoeopathic or excipient ingredient.<br><br>Gluten is a mandatory component of Oat when the route of administration is other than topical and mucosal.  |
| 3524  | OAT BRAN               | E               | Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal.  |
| 3525  | OATMEAL COLLOIDAL      | A, E            | Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal.   |
| 3526  | OCIMENE                | E               | Permitted for use only in combination with other   |

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|   |                        |                 | permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3527  | OCIMENYL ACETATE       | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.   |
| 3528  | 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.<br>The concentration of methyleugenol in the medicine must not exceed 1%.<br>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.<br>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 |

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|   |                             |                 | <p>warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (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:</li> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>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.</p> <p>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.</p> <p>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%.</p> |
| 3529  | OCIMUM<br>KILIMANDSCHARICUM | A, H            | Camphor is a mandatory component of Ocimum kilimandscharicum.   |

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|   |                        |                 | <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p> <p>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:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>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.</p> |
| 3530  | OCIMUM MINIMUM         | A, H            |  |
| 3531  | OCIMUM TENUIFLORUM     | A, H            | <p>When the plant part is oil or distillate, eugenol is a mandatory component of <i>Ocimum tenuiflorum</i>.</p> <p>When the concentration of eugenol in the preparation is more than 25%, the nominal capacity of the container must</p>   |

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|          |                  |          | <p>not be more than 25 millilitres and the following warning statements must be included on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>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.</p> <p>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.</p> <p>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%.</p> |
| 3532     | OCOTEA ODORIFERA | A, H     | <p>Safrole is a mandatory component of Ocotea odorifera.</p> <p>When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.</p> <p>When for topical use then the concentration of safrole in the medicine must be no more than 1%.</p>  |



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| 3533  | OCTACOSANOL  | E               |  |
| 3534  | OCTADECANAL  | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3535  | OCTADECENE/MA COPOLYMER  | E               | Only for use in topical medicines for dermal application.  |
| 3536  | 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.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3537  | OCTAHYDROCOUMARIN  | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |
| 3538  | OCTAN-1-OL   | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than   |

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|   |                         |                 | 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3539  | OCTANAL DIMETHYL ACETAL | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.   |
| 3540  | 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.<br>The concentration in the medicine must be no more than 0.5%.  |
| 3541  | OCTANOIC ACID           | A, E            | When for topical use, the concentration in the medicine must be no more than 2% (w/w).<br>When for excipient use, permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.<br>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.<br>When used in a fragrance, the total fragrance proprietary |

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|   |                        |                 | excipient formulation in a medicine must be no more than 1%.  |
| 3542  | OCTENE-1               | E               | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.<br>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.  |
| 3543  | OCTHILINONE            | E               | Only for use in topical medicines for dermal application.   |
| 3544  | OCTOCRYLENE            | A               | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 10%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 3545  | OCTOXINOL 10           | E               | Only for use in topical medicines for dermal application.   |
| 3546  | OCTYL ACETATE          | E               | Permitted for use only in   |

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|   |                        |                 | <p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>   |
| 3547  | OCTYL CROTONATE        | E               | <p>Octyl crotonate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing octyl crotonate must not be more than 1% of the total medicine.</p> |
| 3548  | OCTYL HYDROXYSTEARATE  | E               | <p>Only for use in topical medicines for dermal application.</p>  |
| 3549  | OCTYL ISOBUTYRATE      | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>  |
| 3550  | OCTYL ISONONANOATE     | E               | <p>Only for use in topical medicines for dermal application.</p>  |
| 3551  | OCTYL METHOXYCINNAMATE | A               | <p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines</p>  |

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|   |                        |                 | intended for use in the eye.<br>The concentration in the medicine must not be more than 10%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).  |
| 3552  | OCTYL PALMITATE        | E               | Only for use in topical medicines for dermal application.  |
| 3553  | OCTYL SALICYLATE       | A               | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 5%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 3554  | OCTYL STEARATE         | E               | Only for use in topical medicines for dermal application.  |

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| 3555  | OCTYLBICYCLOHEPTENEDICARBOXIMIDE  | E               | Only for use in topical medicines for dermal application.<br>The medicine requires the following warning statement on the medicine label:<br>- (OBCARB) 'Contains octylbicycloheptenedicarboximide' (or words to that effect).   |
| 3556  | OCTYLDODECANOL                    | E               | Only for use in topical medicines for dermal application.  |
| 3557  | 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.<br>The concentration in the medicine must be no more than 5%.<br>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection. |
| 3558  | 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.<br>The concentration in the medicine must be no more than 12%.  |
| 3559  | OCTYLDODECYL NEOPENTANOATE        | E               | Only for use in topical medicines for dermal application.  |
| 3560  | OCTYLDODECYL STEARATE             | E               | Only for use in topical medicines for dermal   |

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|   |                        |                 | application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 2%.  |
| 3561  | OCTYLDODECYL XYLOSIDE  | E               | Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 1.5%. |
| 3562  | OENANTHATE             | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.           |
| 3563  | OENANTHE AQUATICA      | H               | Only for use as an active homoeopathic ingredient.<br>The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.  |
| 3564  | OENANTHE CROCATA       | A, H            | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.  |
| 3565  | OENOTHERA BIENNIS      | A, E, H         |   |
| 3566  | OENOTHERA STRICTA      | A, H            |   |
| 3567  | OKOUBAKA AUBREVILLEI   | A, H            |   |
| 3568  | OLDENLANDIA DIFFUSA    | A, E, H         |   |

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| 3569  | OLEA EUROPAEA          | A, E, H         |  |
| 3570  | OLEIC ACID             | E               |  |
| 3571  | OLETH-10               | E               | Only for use in topical medicines for dermal application.  |
| 3572  | OLETH-2                | E               | Only for use in topical medicines for dermal application.<br>Dioxane and Ethylene oxide are mandatory components of Oleth-2.<br>The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.<br>The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%. |
| 3573  | OLETH-20               | E               | Only for use in topical medicines for dermal application.  |
| 3574  | OLETH-3                | E               | Only for use in topical medicines for dermal application.  |
| 3575  | 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.<br>The concentration in the medicine must be no more than 0.12%.   |
| 3576  | OLETH-5                | E               | Only for use in topical medicines for dermal application.  |



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| <b>Item</b>                                     | <b>Ingredient name</b>                 | <b>Purpose</b>  | <b>Specific requirements</b>   |
| 3577  | OLEYL ALCOHOL                          | E               | Only for use in topical medicines for dermal application.  |
| 3578  | OLIBANUM OIL                           | A, E, H         |  |
| 3579  | OLIGOFRUCTOSE                          | A, E            |  |
| 3580  | OLIVE                                  | E               |  |
| 3581  | OLIVE OIL                              | A, E, H         |  |
| 3582  | OMEGA-3 FISH OIL<br>PHYTOSTEROL ESTERS | A               | The medicine requires the following warning statement on the medicine label:<br>- (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'  |
| 3583  | OMEGA-3-ACID ETHYL ESTERS<br>60        | A               | Docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid are mandatory components of omega-3-acid ethyl esters 60.<br>Only to be used in a medicine where DSM Nutritional Products Pty Ltd (Client ID 31685), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 30 June 2021.<br>Only permitted for use in medicines that are for oral routes of administration.<br>The maximum recommended daily dose of the medicine must not provide more than 3750 milligrams of docosahexaenoic acid, |

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|          |                              |          | <p>docosapentaenoic acid and eicosapentaenoic acid combined.</p> <p>The following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect);</li> <li>- (ACOAG) 'Individuals taking anticoagulants should seek medical advice before taking this product' (or words to that effect);</li> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (FOOD) 'To be taken with food' (or words to that effect).</li> </ul>  |
| 3584     | OMEGA-3-ACID ETHYL ESTERS 90 | A        | <p>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: -</p> <ul style="list-style-type: none"> <li>'Individuals taking anticoagulants should seek medical advice before taking this product' (or words to that effect).</li> <li>- 'To be taken with food' (or words to that effect).</li> <li>- 'Not recommended for used by pregnant and lactating women' (or words to that effect).</li> </ul> |

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| <b>Item</b>                                     | <b>Ingredient name</b> | <b>Purpose</b>  | <b>Specific requirements</b>  |
|   |                        |                 | - 'Use in children under 12 years is not recommended' (or words to that effect).  |
| 3585  | ONION                  | E               |   |
| 3586  | ONION OIL              | A, H            |   |
| 3587  | ONONIS SPINOSA         | A, E, H         |   |
| 3588  | ONOPORDUM ACANTHIUM    | A, H            |   |
| 3589  | ONOSMODIUM VIRGINIANUM | A, H            |   |
| 3590  | OPHIOPOGON JAPONICUS   | A, H            |   |
| 3591  | OPOPANAX CHIRONIUM     | A, E, H         | When used as an excipient, permitted for use only in combination with other permitted ingredients as part of a flavour or a fragrance proprietary excipient formulation.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3592  | OPOPANAX OIL           | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 3593  | OPUNTIA FICUS-INDICA   | A, H            |   |
| 3594  | ORANGE                 | E               |   |
| 3595  | ORANGE FLOWER ABSOLUTE | E               | Permitted for use only in combination with other permitted ingredients as a   |

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| <b>Item</b>                                     | <b>Ingredient name</b> | <b>Purpose</b>  | <b>Specific requirements</b>   |
|   |                        |                 | flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.   |
| 3596  | ORANGE FLOWER OIL      | A, E, H         | When used internally, oxdrine is a mandatory component of orange flower oil.<br>The quantity of oxdrine in the maximum recommended daily dose must be no more than 30 milligrams.  |
| 3597  | ORANGE JUICE           | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3598  | ORANGE JUICE OIL       | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3599  | ORANGE OIL             | A, E, H         | When used internally, oxdrine is a mandatory component of orange oil.<br>The quantity of oxdrine in the maximum recommended daily dose must be no more than 30   |

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| <b>Item</b>                                     | <b>Ingredient name</b>           | <b>Purpose</b>  | <b>Specific requirements</b><br>milligrams.   |
| 3600  | ORANGE OIL BITTER                | E               | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavor, the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%.</p> <p>The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' or words to that effect must be include on the medicine label unless the medicine is:</p> <p>a) for internal use;</p> <p>b) in preparations containing 1.4% or less of orange oil bitter;</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p> |
| 3601  | ORANGE OIL BITTER<br>COLDPRESSED | A, E, H         | <p>When used internally, oxedrine is a mandatory component of orange oil bitter coldpressed.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p> <p>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:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 1.4% or less of orange oil bitter coldpressed; or</p>  |

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| <b>Item</b>                                     | <b>Ingredient name</b>  | <b>Purpose</b>  | <b>Specific requirements</b>   |
|   |                         |                 | c) for use in soaps or bath or shower gels that are washed off the skin.   |
| 3602  | ORANGE OIL COLD PRESSED | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3603  | ORANGE OIL DISTILLED    | A, E, H         | When used internally, oxedrine is a mandatory component of orange oil distilled.<br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.   |
| 3604  | ORANGE OIL SWEET        | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3605  | ORANGE OIL TERPENELESS  | A, E, H         | When used internally, oxedrine is a mandatory component of orange oil terpeneless.<br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.   |

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| <b>Item</b>                                     | <b>Ingredient name</b>            | <b>Purpose</b>  | <b>Specific requirements</b>   |
| 3606  | ORANGE PEEL                       | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3607  | ORANGE PEEL DRIED BITTER          | A, E, H         | When used internally, oxedrine is a mandatory component of orange peel dried bitter.<br><br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.   |
| 3608  | ORANGE PEEL OIL SWEET TERPENELESS | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br><br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3609  | ORANGE ROUGHY OIL                 | E               | Only for use in topical medicines for dermal application.  |
| 3610  | ORIGANUM MAJORANA                 | A, H            | Beta-arbutin is a mandatory component of Origanum majorana.<br><br>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.<br><br>When for dermal application exclusively to the face:<br>a) the concentration of beta-                                 |

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| <b>Item</b>                                     | <b>Ingredient name</b> | <b>Purpose</b>  | <b>Specific requirements</b>  |
|   |                        |                 | <p>arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When the plant preparation is oil or distillate, and the concentration of <i>Origanum majorana</i> oil or distillate within the medicine is more than 50%:</p> <p>a) the nominal capacity of the container must not be more than 50 mL;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the following warning statement is required on the label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p> |
| 3611  | ORIGANUM OIL           | E               | <p>Permitted for use only in combination with other ingredients as a fragrance.</p> <p>If used as a fragrance the total concentration in the medicine must be no more than 1%.</p>  |
| 3612  | ORIGANUM OIL SPANISH   | A, E, H         |   |
| 3613  | ORIGANUM VULGARE       | A, E, H         |   |
| 3614  | ORNITHINE              | A, E            |   |
| 3615  | ORNITHINE ASPARTATE    | A, E            |   |
| 3616  | ORNITHINE              | A, E            |   |



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|   | MONOHYDROCHLORIDE          |                 |   |
| 3617  | ORNITHOGALUM<br>UMBELLATUM | A, H            |   |
| 3618  | OROSTACHYS FIMBRIATA       | A, H            |   |
| 3619  | OROXYLUM INDICUM           | A, H            |   |
| 3620  | ORRIS                      | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3621  | ORRIS CONCRETE             | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3622  | ORRIS ROOT EXTRACT         | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3623  | ORRIS ROOT OIL             | A, E, H         |   |
| 3624  | ORRIS ROOT RESIN           | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br><br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3625  | ORTHO-TERT-                | E               | Permitted for use only in   |

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| <b>Item</b>                                     | <b>Ingredient name</b>       | <b>Purpose</b>  | <b>Specific requirements</b>   |
|   | BUTYLCYCLOHEXYL ACETATE      |                 | combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3626  | ORTHOSIPHON ARISTATUS        | A, H            |  |
| 3627  | ORYZA SATIVA                 | A, E, H         |  |
| 3628  | ORYZANOL                     | E               |  |
| 3629  | OSBECKIA CHINENSIS           | A, H            |  |
| 3630  | OSMANTHUS ABSOLUTE           | E               | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3631  | OSMANTHUS FRAGRANS           | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 3632  | OTTELIA ALISMOIDES           | A, H            |  |
| 3633  | OXACYCLOHEPTADEC-11-EN-2-ONE | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.  |

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| 3634  | OXACYCLOHEXADECAN-2-ONE | E               | Only for use in topical medicines for dermal application.   |
| 3635  | OXACYCLOHEXADECEN-2-ONE | E               | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 3636  | OXALIC ACID             | H               | Only for use as an active homoeopathic ingredient.  |
| 3637  | OXALIS ACETOSELLA       | A, H            |   |
| 3638  | OXIDISED MAIZE STARCH   | E               | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 3639  | OXIDISED TAPIOCA STARCH | E               |   |
| 3640  | OXYBENZONE              | A               | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 10%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective |

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|   |                        |                 | clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 3641  | OYSTER                 | E               |   |
| 3642  | OYSTER SHELL           | A, E, H         |   |

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