

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

Volume 3

## 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 |                      |          |  |
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| Column 1                                 | Column 2             | Column 3 | Column 4   |
| Item                                     | Ingredient name      | Purpose  | Specific requirements  |
| 2159                                     | FABIANA IMBRICATA    | A, H     |  |
| 2160                                     | FAGOPYRUM ESCULENTUM | A, H     |  |
| 2161                                     | FAGUS GRANDIFOLIA    | A, H     |  |
| 2162                                     | FAGUS SYLVATICA      | A, H     |  |
| 2163                                     | FALLOPIA MULTIFLORA  | A, H     | When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (FALLMUL) 'Warning: Fallopia multiflora may harm the liver in some people. Use under the supervision of a healthcare professional.'   |
| 2164                                     | FARNESOL             | 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%. |
| 2165                                     | FARNESYL ACETATE     | E        | Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient   |

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| Column 1                                 | Column 2        | Column 3 | Column 4  |
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|  |                 |          | <p>formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>                                     |
| 2166                                     | FAST GREEN FCF  | E        | Permitted for use only as a colour in medicines limited to topical and oral routes of administration.   |
| 2167                                     | FENCHONE        | 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> |
| 2168                                     | FENCHYL ACETATE | 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>  |

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| Column 1                                 | Column 2               | Column 3 | Column 4  |
| Item                                     | Ingredient name        | Purpose  | Specific requirements   |
| 2169                                     | FENCHYL ALCOHOL        | 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>   |
| 2170                                     | FENNEL BITTER SEED DRY | A, E, H  | <p>When used in oral medicines, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended'</li> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'</li> <li>- (BREASF) 'Do not use while breastfeeding.'</li> </ul> |
| 2171                                     | FENNEL LEAF            | E        |   |
| 2172                                     | FENNEL OIL             | A, E, H  | <p>Methyl chavicol is a mandatory component of fennel oil.</p> <p>When the concentration of methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL, a restricted flow insert must be fitted on the container, and the following warning</p>   |

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| Column 1                                 | Column 2              | Column 3 | Column 4  |
| Item                                     | Ingredient name       | Purpose  | Specific requirements   |
|  |                       |          | <p>statement is required on the label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children (or words to that effect).'</li> </ul> <p>The maximum daily dose must provide no more than 150 mg of fennel oil.</p> <p>When used in oral medicines, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended.'</li> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect).'</li> <li>- (BREASF) 'Do not use while breastfeeding.'</li> </ul> |
| 2173                                     | FENNEL SWEET SEED DRY | A, E, H  | <p>When used in oral medicines, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended'</li> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'</li> <li>- (BREASF) 'Do not use while breastfeeding.'</li> </ul>   |
| 2174                                     | FENUGREEK             | E        | Permitted for use only in combination with other  |

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| Item                                     | Ingredient name         | Purpose  | Specific requirements   |
|  |                         |          | permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  |
| 2175                                     | FENUGREEK OIL           | E        | Fenugreek oil is permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 2176                                     | FERRIC AMMONIUM CITRATE | A, E, H  | When for internal use, iron is a mandatory component of ferric ammonium citrate.<br>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.<br>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.<br>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).<br>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total |

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| Column 1                                 | Column 2        | Column 3 | Column 4  |
| Item                                     | Ingredient name | Purpose  | Specific requirements   |
|  |                 |          | <p>contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |
| 2177                                     | FERRIC CHLORIDE | A, E, H  | <p>When for internal use, iron is a mandatory component of ferric chloride.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no</p>  |

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| Item                                     | Ingredient name                | Purpose  | Specific requirements  |
|  |                                |          | <p>more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |
| 2178                                     | FERRIC CHLORIDE<br>HEXAHYDRATE | A, E, H  | <p>When for internal use, iron is a mandatory component of ferric chloride hexahydrate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p>  |

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| Column 1                                 | Column 2        | Column 3 | Column 4   |
| Item                                     | Ingredient name | Purpose  | Specific requirements  |
|  |                 |          | <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |

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| Item                                     | Ingredient name         | Purpose  | Specific requirements   |
| 2179                                     | FERRIC GLYCEROPHOSPHATE | A, E, H  | <p>When for internal use, iron is a mandatory component of ferric glycerophosphate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional</p> |

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| Item                                     | Ingredient name      | Purpose  | Specific requirements  |
|  |                      |          | support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:<br><br>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).   |
| 2180                                     | FERRIC OXIDE         | E        |  |
| 2181                                     | FERRIC PHOSPHATE     | H        | Only for use as an active homoeopathic ingredient.   |
| 2182                                     | FERRIC PYROPHOSPHATE | A, H     | When for internal use, iron is a mandatory component of ferric pyrophosphate.<br><br>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.<br><br>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.<br><br>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).<br><br>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of |

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| Item                                     | Ingredient name         | Purpose  | Specific requirements  |
|  |                         |          | <p>elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |
| 2183                                     | FERROSOFERRIC OXIDE     | E        | <p>When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.</p>   |
| 2184                                     | FERROSOFERRIC PHOSPHATE | H        | Only for use as an active homoeopathic ingredient.   |

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| <b>Column 1</b>                                 | <b>Column 2</b>        | <b>Column 3</b> | <b>Column 4</b>   |
| <b>Item</b>                                     | <b>Ingredient name</b> | <b>Purpose</b>  | <b>Specific requirements</b>  |
| 2185  | FERROUS FUMARATE       | A, H            | <p>When for internal use, iron is a mandatory component of ferrous fumarate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related</p> |

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| Column 1                                 | Column 2          | Column 3 | Column 4   |
| Item                                     | Ingredient name   | Purpose  | Specific requirements  |
|  |                   |          | claims, the medicine requires the following statement on the medicine label:<br>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).   |
| 2186                                     | FERROUS GLUCONATE | A, E, H  | When for internal use, iron is a mandatory component of ferrous gluconate.<br>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.<br>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.<br>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).<br>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.<br>Undivided preparations containing more than 250 mg of elemental iron in the total |

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| Column 1                                 | Column 2                    | Column 3 | Column 4  |
| Item                                     | Ingredient name             | Purpose  | Specific requirements   |
|  |                             |          | <p>contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>   |
| 2187                                     | FERROUS GLUCONATE DIHYDRATE | A, E, H  | <p>When for internal use, iron is a mandatory component of ferrous gluconate dihydrate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a</p> |

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| Column 1                                 | Column 2                   | Column 3 | Column 4  |
| Item                                     | Ingredient name            | Purpose  | Specific requirements   |
|  |                            |          | <p>dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |
| 2188                                     | FERROUS IODIDE             | H        | Only for use as an active homoeopathic ingredient.  |
| 2189                                     | FERROUS LACTATE TRIHYDRATE | A, E, H  | <p>When for internal use, iron is a mandatory component of ferrous lactate trihydrate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of</p>   |

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|  |                 |          | <p>iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |

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| Column 1                                 | Column 2                         | Column 3 | Column 4   |
| Item                                     | Ingredient name                  | Purpose  | Specific requirements  |
| 2190                                     | FERROUS PHOSPHATE<br>OCTAHYDRATE | A, E, H  | <p>When for internal use, iron is a mandatory component of ferrous phosphate octahydrate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related</p> |

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| Column 1                                 | Column 2        | Column 3 | Column 4   |
| Item                                     | Ingredient name | Purpose  | Specific requirements  |
|  |                 |          | claims, the medicine requires the following statement on the medicine label:<br>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).   |
| 2191                                     | FERROUS PICRATE | H        | Only for use as an active homoeopathic ingredient.   |
| 2192                                     | FERROUS SULFATE | A, E, H  | When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.<br>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.<br>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).<br>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.<br>Undivided preparations |

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| Item                                     | Ingredient name                 | Purpose  | Specific requirements  |
|  |                                 |          | <p>containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>   |
| 2193                                     | FERROUS SULFATE<br>HEPTAHYDRATE | A, E, H  | <p>When for internal use, iron is a mandatory component of ferrous sulfate heptahydrate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a</p> |

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| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
|  |                     |          | <p>dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |
| 2194                                     | FERULA ASSA-FOETIDA | A, E, H  |   |
| 2195                                     | FERULA FOETIDA      | A, E, H  |   |
| 2196                                     | FERULA GALBANIFLUA  | A, E, H  |   |
| 2197                                     | FERULA RUBRICAULIS  | A, E, H  |   |
| 2198                                     | FERULA SUMBUL       | A, H     |   |
| 2199                                     | FERULIC ACID        | E        | Only for use in topical medicines for dermal application.   |

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| 2200                                     | FESTUCA ELATIOR      | A, H     |   |
| 2201                                     | FEVERFEW HERB DRY    | A, H     |   |
| 2202                                     | FEVERFEW HERB POWDER | A, H     |   |
| 2203                                     | FICUS CARICA         | A, E, H  |   |
| 2204                                     | FICUS PUMILA         | A, H     |   |
| 2205                                     | FIG                  | E        |   |
| 2206                                     | FIG DRY              | A, H     |   |
| 2207                                     | FILIPENDULA ULMARIA  | A, H     | <p>Methyl salicylate is a mandatory component of Filipendula ulmaria.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>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.</p> <p>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</li> </ul> |

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|  |                 |          | 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 application:<br>i) the concentration of methyl salicylate in the medicine must not be more than 25%;<br>ii) 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);<br>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or 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 |

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|  |                                  |          | statement is required on the medicine label:<br>- (IRRIT) 'If irritation develops, discontinue use'.   |
| 2208                                     | FIR BALSAM ABSOLUTE              | 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%.  |
| 2209                                     | FIR NEEDLE OIL CANADIAN          | A, E     |  |
| 2210                                     | FIR NEEDLE OIL SIBERIAN          | A, E     |  |
| 2211                                     | FIRMIANA SIMPLEX                 | A, E, H  |  |
| 2212                                     | FISH OIL - RICH IN OMEGA-3 ACIDS | A        | Only for use in oral medicines.  |
| 2213                                     | FLEMINGIA MACROPHYLLA            | A, H     |  |
| 2214                                     | FLOUVE 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 medicine must be no more 1%. |
| 2215                                     | FLUORESCEIN SODIUM               | E        |  |
| 2216                                     | FOENICULUM VULGARE               | A, E, H  | When used in oral medicines, the following warning statements are required on the  |

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|  |                 |          | <p>label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended'</li> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'</li> <li>- (BREASF) 'Do not use while breastfeeding.'</li> </ul> <p>When the plant preparation is oil or distillate, methyl chavicol is a mandatory component and the maximum daily dose must provide no more than 150 mg of the plant preparation.</p> <p>When the plant preparation is oil or distillate and the concentration of methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL, a restricted flow insert must be fitted on the container, and the following warning statement is required on the label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect).</li> </ul> |
| 2217                                     | FOLIC ACID      | A        | <p>When for internal use, the maximum recommended daily dose must be no more than 500 micrograms of folic acid.</p> <p>When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in</p>   |

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| Item                                     | Ingredient name         | Purpose  | Specific requirements  |
|  |                         |          | <p>combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.</p> <p>When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects:</p> <p>a) the maximum daily dose must provide 400 – 500 micrograms of folic acid; and</p> <p>b) the following statement must be included on the label:</p> <p>- (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)'.</p> |
| 2218                                     | FOOD ORANGE 6           | E        | Permitted for use only as a colour in medicines limited to topical and oral routes of administration.  |
| 2219                                     | FOOD ORANGE 7           | E        | Permitted for use only as a colour in medicines limited to topical and oral routes of administration.  |
| 2220                                     | FOOD RED 13             | E        | Permitted for use only as a colour for topical use.  |
| 2221                                     | FORMALDEHYDE/MELAMINE/T | E        | Only for use in topical  |

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| <b>Item</b>                                     | <b>Ingredient name</b>       | <b>Purpose</b>  | <b>Specific requirements</b>  |
|   | OSYLAMIDE COPOLYMER          |                 | medicines for dermal application.<br>The concentration in the medicine must be no more than 10%.  |
| 2222  | FORMIC ACID                  | H               | Only for use as an active homoeopathic ingredient.  |
| 2223  | FORSYTHIA SUSPENS            | A, H            |   |
| 2224  | FORTIFIED WINE               | E               | Ethanol is a mandatory component of fortified wine.<br>When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:<br>- (ETHAN) 'Contains ethanol or contains alcohol'. |
| 2225  | FRACTIONATED COCONUT OIL     | E               |   |
| 2226  | FRACTIONATED PALM KERNEL OIL | 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.     |
| 2227  | FRAGARIA CHILOENSIS          | A, E, H         |   |
| 2228  | FRAGARIA VESCA               | A, E, H         |   |

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| 2229                                     | FRAGARIA VIRGINIANA | A, E, H  |   |
| 2230                                     | FRAGARIA X ANANASSA | A, E, H  |   |
| 2231                                     | FRANGULA BARK DRY   | A, H     | <p>Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' [or words to that effect].</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements</p> |

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| Item                                     | Ingredient name      | Purpose  | Specific requirements  |
|  |                      |          | <p>on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul> |
| 2232                                     | FRANGULA BARK POWDER | A, H     | <p>Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not</li> </ul>  |

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| Item                                     | Ingredient name | Purpose  | Specific requirements  |
|  |                 |          | <p>recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]';</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water [or words to that effect]';</p> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> |

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| Item                                     | Ingredient name    | Purpose  | Specific requirements   |
|  |                    |          | <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water [or words to that effect]'; and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>   |
| 2233                                     | FRANGULA PURSHIANA | A, H     | <p>When for oral use, hydroxyanthracene derivatives calculated as cascarioside A is a mandatory component of Frangula purshiana.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].</p> <p>When promoted or marketed as a laxative, the medicine</p> |

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| Column 1                                 | Column 2                                | Column 3 | Column 4  |
| Item                                     | Ingredient name                         | Purpose  | Specific requirements   |
|  |   |          | <p>requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' [or words to that effect].</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul> |
| 2234                                     | FRAXINUS AMERICANA                      | A, H     |   |
| 2235                                     | FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA | A, H     |   |
| 2236                                     | FRAXINUS EXCELSIOR                      | A, H     | The components Nuzhenide and secoiridoid glucoside GL3  |

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|  |                          |          | are only available when the plant part is seed.  |
| 2237                                     | FRAXINUS ORNUS           | A, H     |  |
| 2238                                     | FRITILLARIA CIRRHOSA     | A, H     |  |
| 2239                                     | FRITILLARIA THUNBERGII   | A, H     |  |
| 2240                                     | FRITILLARIA VERTICILLATA | A, H     |  |
| 2241                                     | FRUCTOOLIGOSACCHARIDES   | A, E     |  |
| 2242                                     | FRUCTOSE                 | A, E, H  |  |
| 2243                                     | FUCUS VESICULOSUS        | A, E, H  | Iodine is a mandatory component of Fucus vesiculosus.<br>Only for external use when the concentration of available 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. |
| 2244                                     | FUMARIA OFFICINALIS      | A, E, H  |  |
| 2245                                     | FUMARIC ACID             | E, H     | Only for use as an active homoeopathic or excipient ingredient.  |
| 2246                                     | FUMITORY HERB DRY        | A, H     |  |
| 2247                                     | FUMITORY HERB POWDER     | A, H     |  |
| 2248                                     | FURAMINTON               | E        | Permitted for use only in combination with other   |

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| Item                                     | Ingredient name    | Purpose  | Specific requirements  |
|  |                    |          | permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 2249                                     | FURFURAL           | 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%. |
| 2250                                     | FURFURYL ACETATE   | 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%.  |
| 2251                                     | FURFURYL ALCOHOL   | 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%.  |
| 2252                                     | FURFURYL MERCAPTAN | E        | Permitted for use only in  |

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| Item                                     | Ingredient name | Purpose  | Specific requirements   |
|  |                 |          | <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>  |
| 2253                                     | FUSEL OIL       | 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>  |
| 2254                                     | GALBANUM OIL    | 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> |
| 2255                                     | GALBANUM PHENOL | 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>  |

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| Item                                     | Ingredient name    | Purpose  | Specific requirements  |
| 2256                                     | GALBANUM 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%.  |
| 2257                                     | GALBANUM RESINOID  | 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%. |
| 2258                                     | GALEGA OFFICINALIS | A, H     |  |
| 2259                                     | GALEOPSIS SEGETUM  | A, H     |  |
| 2260                                     | GALIUM APARINE     | A, H     |  |
| 2261                                     | GALIUM ODORATUM    | A, H     | When used as an active ingredient coumarin is a mandatory component of Galium odoratum and the concentration of coumarin in the medicine must be no more than 0.001%.  |
| 2262                                     | GALIUM PALUSTRE    | A, H     |  |
| 2263                                     | GALIUM VERUM       | A, H     |  |
| 2264                                     | GALL STONE         | H        | Only for use as an active  |

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| Item                                     | Ingredient name                           | Purpose  | Specific requirements  |
|  |   |          | homoeopathic ingredient.   |
| 2265                                     | GALPHIMIA GLAUCA                          | A, H     |  |
| 2266                                     | GAMMA-4-DIMETHYL-3-CYCLOHEXENE-1-PROPANOL | 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%.  |
| 2267                                     | GAMMA-BUTYROLACTONE                       | 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%.  |
| 2268                                     | GAMMA-CYCLODEXTRIN                        | E        |  |
| 2269                                     | GAMMA-DECALACTONE                         | 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><br>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. |

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| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
| 2270                                     | GAMMA-DODECALACTONE | 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> |
| 2271                                     | GAMMA-HEPTALACTONE  | 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> |
| 2272                                     | GAMMA-HEXALACTONE   | 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> |
| 2273                                     | GAMMA-IONONE        | E        | Permitted for use only in combination with other  |

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| Column 1                                 | Column 2              | Column 3 | Column 4   |
| Item                                     | Ingredient name       | Purpose  | Specific requirements  |
|  |                       |          | 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%.  |
| 2274                                     | GAMMA-LINOLEIC ACID   | E        | Only for use in topical medicines for dermal application.  |
| 2275                                     | GAMMA-LINOLENIC ACID  | E        |  |
| 2276                                     | GAMMA-N-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 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2277                                     | GAMMA-NONALACTONE     | 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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| Item                                     | Ingredient name     | Purpose  | Specific requirements  |
|  |                     |          | medicine must be no more 1%.   |
| 2278                                     | GAMMA-OCTALACTONE   | 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%. |
| 2279                                     | GAMMA-TERPINENE     | 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%. |
| 2280                                     | GAMMA-TOCOPHEROL    | E        |  |
| 2281                                     | GAMMA-UNDECALACTONE | 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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| Item                                     | Ingredient name                       | Purpose  | Specific requirements   |
| 2282                                     | GAMMA-VALEROLACTONE                   | 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%.                           |
| 2283                                     | GANODERMA LUCIDUM                     | A, E, H  |   |
| 2284                                     | GARCINIA GUMMI-GUTTA                  | A        | Only for use in oral medicines.<br>Must be obtained from the rind of the fruit only.<br>Must not contain any directions for use for children or pregnant or lactating women.                                      |
| 2285                                     | GARCINIA QUAESITA                     | A, H     |   |
| 2286                                     | GARDEN BEAN                           | E        |   |
| 2287                                     | GARDENIA JASMINOIDES                  | A, E     |   |
| 2288                                     | GARDENIA TAHITENSIS<br>FLOWER EXTRACT | 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 0.002% |
| 2289                                     | GARLIC BULB DRY                       | A, E, H  |   |
| 2290                                     | GARLIC BULB FRESH                     | A, H     |   |
| 2291                                     | GARLIC BULB POWDER                    | A, E, H  |   |

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| Item                                     | Ingredient name       | Purpose  | Specific requirements  |
| 2292                                     | GARLIC CLOVE POWDER   | A, H     |  |
| 2293                                     | GARLIC OIL            | A, E, H  |  |
| 2294                                     | GASTRODIA ELATA       | A, H     |  |
| 2295                                     | GAULTHERIA PROCUMBENS | A, E, H  | <p>Methyl salicylate is a mandatory component of <i>Gaultheria procumbens</i>.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>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.</p> <p>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>The following warning statement is required on the</p> |

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| Item                                     | Ingredient name | Purpose  | Specific requirements   |
|  |                 |          | <p>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 medicine label: <ul style="list-style-type: none"> <li>- (IRRIT) 'If irritation develops, discontinue use'.</li> </ul> </li> </ul> |
| 2296                                     | GELATIN         | A, E     |   |

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| Item                                     | Ingredient name        | Purpose  | Specific requirements  |
| 2297                                     | GELIDIUM AMANSII       | A, H     | <p>Iodine is a mandatory component of Gelidium amansii.</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> |
| 2298                                     | GELLAN GUM             | E        |  |
| 2299                                     | GELSEMIUM DRY          | A, H     | The concentration of Gelsemium dry in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.  |
| 2300                                     | GELSEMIUM POWDER       | A, H     |  |
| 2301                                     | GELSEMIUM SEMPERVIRENS | A, H     | The concentration of equivalent dry Gelsemium sempervirens in the product must be no more than 1mg/Kg or 1mg/L or 0.0001%.   |
| 2302                                     | GENET ABSOLUTE         | 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>                      |

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| Item                                     | Ingredient name      | Purpose  | Specific requirements  |
| 2303                                     | GENTIAN DRY          | A, H     |  |
| 2304                                     | GENTIAN POWDER       | A, H     |  |
| 2305                                     | GENTIANA LUTEA       | A, E, H  |  |
| 2306                                     | GENTIANA MACROPHYLLA | A, H     |  |
| 2307                                     | GENTIANA RHODANTHA   | A, H     |  |
| 2308                                     | GENTIANA SCABRA      | A, H     |  |
| 2309                                     | GENTIANELLA AMARELLA | A, H     |  |
| 2310                                     | GERANIAL             | 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%.                          |
| 2311                                     | GERANIC ACID         | 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%.                    |
| 2312                                     | GERANIOL             | 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. |

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| Item                                     | Ingredient name          | Purpose  | Specific requirements   |
|  |                          |          | When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.  |
| 2313                                     | GERANIUM                 | 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%. |
| 2314                                     | GERANIUM MACULATUM       | A, E, H  |   |
| 2315                                     | GERANIUM OIL             | A, E, H  |   |
| 2316                                     | GERANIUM OIL SAPONIFIED  | 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%. |
| 2317                                     | GERANIUM OIL TERPENELESS | 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%. |
| 2318                                     | GERANIUM ROBERTIANUM     | A, E, H  |   |
| 2319                                     | GERANIUM ROSE OIL        | E        | Permitted for use only in   |

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| Item                                     | Ingredient name    | Purpose  | Specific requirements   |
|  |                    |          | <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>  |
| 2320                                     | GERANIUM SIBIRICUM | A, E, H  |   |
| 2321                                     | GERANYL ACETATE    | 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> |
| 2322                                     | GERANYL ACETONE    | 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> |
| 2323                                     | GERANYL BUTYRATE   | E        | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p>  |

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| Column 1                                 | Column 2            | Column 3 | Column 4  |
| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
|  |                     |          | <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>  |
| 2324                                     | GERANYL CROTONATE   | 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>  |
| 2325                                     | GERANYL ETHYL ETHER | 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>  |
| 2326                                     | GERANYL FORMATE     | 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> |

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| 2327                                     | GERANYL ISOBUTYRATE | 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%. |
| 2328                                     | GERANYL ISOVALERATE | 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%. |
| 2329                                     | GERANYL NITRILE     | 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%.  |
| 2330                                     | GERANYL PROPIONATE  | E        | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  |

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| Item                                     | Ingredient name     | Purpose  | Specific requirements  |
|  |                     |          | <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>   |
| 2331                                     | GERANYL TIGLATE     | 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>   |
| 2332                                     | GEUM RIVALE         | A, H     |  |
| 2333                                     | GEUM URBANUM        | A, H     |  |
| 2334                                     | GHATTI GUM          | A, E, H  |  |
| 2335                                     | GIGARTINA MAMILLOSA | A, H     | <p>Iodine is a mandatory component of Gigartina mamilliosa.</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> |
| 2336                                     | GINGER DRY          | A, E, H  |  |

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| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
| 2337                                     | GINGER OIL          | A, E, H  |   |
| 2338                                     | GINGER OLEORESIN    | 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 the medicine must be no more than 5%.   |
| 2339                                     | GINGER POWDER       | A, E, H  |   |
| 2340                                     | GINKGO BILOBA       | A, E, H  | The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27), as in force or existing from time to time. This condition does not apply to powdered or dried leaf. |
| 2341                                     | GLACIAL ACETIC ACID | E, H     | The concentration in the medicine must be no more than 1.5%.  |
| 2342                                     | GLECHOMA HEDERACEA  | A, H     |   |
| 2343                                     | GLECHOMA LONGITUBA  | A, H     |   |
| 2344                                     | GLEDITSIA AUSTRALIS | A, H     |   |
| 2345                                     | GLEDITSIA SINENSIS  | A, H     |   |
| 2346                                     | GLEHNNIA LITTORALIS | A, H     |   |

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| Item                                     | Ingredient name                        | Purpose  | Specific requirements  |
| 2347                                     | GLORIOSA SUPERBA                       | A, H     | Colchicine is a mandatory component of <i>Gloriosa superba</i> and must be declared in the application.<br><br>The concentration of colchicine in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.                          |
| 2348                                     | GLUCOMANNAN                            | E        | Only for use when the dosage form is other than tablet.  |
| 2349                                     | GLUCONOLACTONE                         | E        |  |
| 2350                                     | GLUCOSAMINE HYDROCHLORIDE              | A, E     | When derived from seafood, the medicine requires the following warning statement on the medicine label:<br>- (SFOOD) 'Derived from seafood'.   |
| 2351                                     | GLUCOSAMINE SULFATE                    | A        | When derived from seafood, the medicine requires the following warning statement on the medicine label:<br>- (SFOOD) 'Derived from seafood'.   |
| 2352                                     | GLUCOSAMINE SULFATE POTASSIUM CHLORIDE | A        | Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride.<br><br>When derived from seafood, the medicine requires the following warning statement on the medicine label:<br>- (SFOOD) 'Derived from seafood'. |

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| Column 1                                 | Column 2                               | Column 3 | Column 4   |
| Item                                     | Ingredient name                        | Purpose  | Specific requirements  |
|  |  |          | When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (POTAS) 'Contains [amount of potassium in milligrams] mg of potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'   |
| 2353                                     | GLUCOSAMINE SULFATE<br>SODIUM CHLORIDE | A        | When derived from seafood, the medicine requires the following warning statement on the medicine label:<br>- (SFOOD) 'Derived from seafood'.   |
| 2354                                     | GLUCOSE                                | A, E, H  | 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 |

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| Column 1                                 | Column 2            | Column 3 | Column 4  |
| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
|  |                     |          | the following warning statement on the medicine label:<br>- (LACT) 'Contains lactose' (or words to that effect).  |
| 2355                                     | GLUCOSE GLUTAMATE   | E        | Only for use in topical medicines for dermal application.   |
| 2356                                     | GLUCOSE MONOHYDRATE | A, E, H  | When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose monohydrate, 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). |
| 2357                                     | GLUCOSYLROUTIN      | E        | Only for use in topical medicines for dermal application and not to be  |

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| Column 1                                 | Column 2                       | Column 3 | Column 4  |
| Item                                     | Ingredient name                | Purpose  | Specific requirements   |
|  |                                |          | included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%.  |
| 2358                                     | GLUTAMIC ACID                  | A, E     | Only for use in topical medicines for dermal application.   |
| 2359                                     | GLUTAMIC ACID<br>HYDROCHLORIDE | A, E, H  |   |
| 2360                                     | GLUTAMINE                      | A, E, H  |   |
| 2361                                     | GLUTARAL                       | 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%.   |
| 2362                                     | GLUTATHIONE                    | A, E     | When used as an active ingredient, glutathione can only be used in medicines with an oral route of administration and must be indicated for use in adults only and not in pregnant or lactating women.<br>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)<br>- (ADULT) 'Adults only' (or |

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| Column 1                                 | Column 2   | Column 3 | Column 4   |
| Item                                     | Ingredient name                                    | Purpose  | Specific requirements  |
|  |  |          | words to that effect).   |
| 2363                                     | GLUTEN-FREE WHEAT STARCH                           | E        |  |
| 2364                                     | GLYCERETH-26                                       | 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 7%.  |
| 2365                                     | GLYCEROL   | A, E     | When used as an active ingredient, it is only for use in topical medicines for dermal application.   |
| 2366                                     | GLYCEROL ESTER OF PARTIALLY HYDROGENATED GUM ROSIN | E        | Only for use when the dosage form is 'chewing gum'.<br>Must comply with:<br>a) the Glycerol Ester of Partially Hydrogenated Gum Rosin monograph in the Food Chemicals Codex published by the United States Pharmacopoeial Convention, as in force or existing from time to time; and<br>b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopoeia-National Formulary, as in force or existing from time to time. |
| 2367                                     | GLYCERYL BEHENATE                                  | E        | Behenic acid is a mandatory component of glyceryl behenate.  |

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| Column 1                                 | Column 2               | Column 3 | Column 4  |
| Item                                     | Ingredient name        | Purpose  | Specific requirements   |
|  |                        |          | When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.<br><br>In medicines for topical use, the concentration of glyceryl behenate must be no more than 5%. |
| 2368                                     | GLYCERYL CAPRYLATE     | 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 1%.                                   |
| 2369                                     | GLYCERYL DIISOSTEARATE | E        | For use in topical medicines for dermal application.  |
| 2370                                     | GLYCERYL DILAURATE     | E        | Only for use in topical medicines for dermal application.   |
| 2371                                     | GLYCERYL DIOLEATE      | E        | Only for use in topical medicines for dermal application.   |
| 2372                                     | GLYCERYL DISTEARATE    | E        | Only for use in topical medicines for dermal application.   |
| 2373                                     | GLYCERYL GLUCOSIDE     | E        | Only for use in topical medicines for dermal  |

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| Column 1                                 | Column 2                | Column 3 | Column 4  |
| Item                                     | Ingredient name         | Purpose  | Specific requirements   |
|  |                         |          | application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%.  |
| 2374                                     | GLYCERYL ISOSTEARATE    | 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 5.5%. |
| 2375                                     | GLYCERYL LAURATE        | E        | Only for use in topical medicines for dermal application.   |
| 2376                                     | GLYCERYL LINOLEATE      | E        | Only for use in topical medicines for dermal application.   |
| 2377                                     | GLYCERYL LINOLENATE     | E        | Only for use in topical medicines for dermal application.   |
| 2378                                     | GLYCERYL MONOLEATE      | E        |   |
| 2379                                     | GLYCERYL MONOSTEARATE   | E        |   |
| 2380                                     | GLYCERYL MYRISTATE      | E        | Only for use in topical medicines for dermal application.   |
| 2381                                     | GLYCERYL OLEATE CITRATE | E        | Only for use in topical medicines for dermal application.   |

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| Item                                     | Ingredient name               | Purpose  | Specific requirements  |
|  |                               |          | 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 4% of the formulation.  |
| 2382                                     | GLYCERYL PALMITO-<br>STEARATE | E        |  |
| 2383                                     | GLYCERYL POLYACRYLATE         | 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 0.15%.   |
| 2384                                     | GLYCERYL<br>POLYMETHACRYLATE  | E        | Only for use in topical medicines for dermal application.  |
| 2385                                     | GLYCERYL RICINOLEATE          | E        | Only for use in topical medicines for dermal application.  |
| 2386                                     | GLYCERYL ROSINATE             | E        | Only for use when the dosage form is 'chewing gum'.<br>Must comply with:<br>a) the Glycerol Ester of Gum Rosin monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and |

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| Item                                     | Ingredient name                    | Purpose  | Specific requirements  |
|  |                                    |          | b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopoeia National Formulary, as in force or existing from time to time.                         |
| 2387                                     | GLYCERYL SORBITAN OLEOSTEARATE     | E        | Only for use in topical medicines for dermal application.  |
| 2388                                     | GLYCERYL STARCH                    | E        | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 4%.<br>The residual levels of epichlorohydrin are to be kept below the level of detection. |
| 2389                                     | GLYCERYL STEARATE CITRATE          | E        | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 5%.  |
| 2390                                     | GLYCERYL TRIACETYL HYDROXYSTEARATE | E        | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 6%.  |
| 2391                                     | GLYCERYL TRIACETYL RICINOLEATE     | E        | Only for use in topical medicines for dermal   |

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| Item                                     | Ingredient name       | Purpose  | Specific requirements   |
|  |                       |          | application.  |
| 2392                                     | GLYCERYL TRINITRATE   | H        | Only for use as an active homoeopathic ingredient.  |
| 2393                                     | GLYCERYL UNDECYLENATE | E        | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration of glyceryl undecylenate in a medicine must be no more than 3%.  |
| 2394                                     | GLYCINE               | A, E     |   |
| 2395                                     | GLYCINE MAX           | A, E, H  |   |
| 2396                                     | GLYCOGEN              | E        | Only for use in topical medicines for dermal application.   |
| 2397                                     | GLYCOL DISTEARATE     | E        | Only for use in topical medicines for dermal application.   |
| 2398                                     | GLYCOLIC ACID         | E        | Only for use in topical medicines for dermal application.<br>Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.<br>When present as an excipient in sunscreens, the |

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|  |                         |          | <p>concentration in the medicine must be no more than 5%.</p> <p>When used as an excipient ingredient in other medicines the concentration in the medicine must be no more than 20%.</p> <p>If the concentration is more than 5% but no more than 20%, the pH of the medicine must be 3.5 or greater.</p> |
| 2399                                     | GLYCYRRHIZA GLABRA      | A, E, H  |   |
| 2400                                     | GLYCYRRHIZA SPECIES     | 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>  |
| 2401                                     | GLYCYRRHIZA URALENSIS   | A, E, H  |   |
| 2402                                     | GLYCYRRHIZINIC ACID     | E        |   |
| 2403                                     | GNAPHALIUM AFFINE       | A, H     |   |
| 2404                                     | GNAPHALIUM POLYCEPHALUM | A, H     |   |
| 2405                                     | GNAPHALIUM ULIGINOSUM   | A, H     |   |
| 2406                                     | GOAT                    | H        | Only for use as an active homoeopathic ingredient.  |
| 2407                                     | GOAT MILK               | E        | <p>If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or</p>  |

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| <b>Item</b>                                     | <b>Ingredient name</b>  | <b>Purpose</b>  | <b>Specific requirements</b>  |
|   |                         |                 | words to that effect).  |
| 2408  | GOLD                    | E, H            | Only for use as an active homoeopathic or excipient ingredient.   |
| 2409  | GOLD CHLORIDE           | H               | Only for use as an active homoeopathic ingredient.  |
| 2410  | GOLDEN ROD HERB DRY     | A, E, H         |   |
| 2411  | GOLDEN SEAL ROOT DRY    | A, H            |   |
| 2412  | GOLDEN SEAL ROOT POWDER | A, H            |   |
| 2413  | GOLDEN SYRUP            | E               | <p>Sucrose is a mandatory component of Golden syrup when the route of administration of the medicine is oral or sublingual.</p> <p>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:</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</p> |

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|  |                     |          | the following warning statement on the medicine label:<br>- (LACT) 'Contains lactose' (or words to that effect).  |
| 2414                                     | GOMPHRENA GLOBOSA   | A, H     |   |
| 2415                                     | GOOSEBERRY          | E        |   |
| 2416                                     | GOSSYPIUM HERBACEUM | A, E, H  |   |
| 2417                                     | GRAPE               | E        |   |
| 2418                                     | GRAPE SEED OIL      | E        |   |
| 2419                                     | GRAPE WINE RED      | E        | Ethanol is a mandatory component of Grape wine red.<br>When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:<br>- (ETHAN) 'Contains ethanol' or 'contains alcohol'    |
| 2420                                     | GRAPE WINE SHERRY   | E        | Ethanol is a mandatory component of Grape wine sherry.<br>When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:<br>- (ETHAN) 'Contains ethanol' or 'contains alcohol' |
| 2421                                     | GRAPE WINE WHITE    | E        | Ethanol is a mandatory component of Grape wine  |

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|  |                               |          | white.<br>When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:<br>- (ETHAN) 'Contains ethanol' or 'contains alcohol'  |
| 2422                                     | GRAPEFRUIT                    | E        |  |
| 2423                                     | GRAPEFRUIT 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%. |
| 2424                                     | GRAPEFRUIT OIL<br>COLDPRESSED | A, E, H  |  |
| 2425                                     | GRAPEFRUIT OIL<br>CONCENTRATE | 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%.  |
| 2426                                     | GRAPEFRUIT OIL TERPENELESS    | 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%.  |
| 2427                                     | GRAPEFRUIT 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%. |
| 2428                                     | GRAPHITE                               | H        | Only for use as an active homoeopathic ingredient.   |
| 2429                                     | GRATIOLA LINIFOLIA                     | A, H     |  |
| 2430                                     | GREATER NETTLE HERB DRY                | A, H     |  |
| 2431                                     | GREATER NETTLE HERB POWDER             | A, H     |  |
| 2432                                     | GREATER NETTLE ROOT DRY                | A, H     |  |
| 2433                                     | GREATER NETTLE ROOT POWDER             | A, H     |  |
| 2434                                     | GREEN LIPPED MUSSEL                    | A        |  |
| 2435                                     | GREEN LIPPED MUSSEL DRIED              | A        |  |
| 2436                                     | GREEN LIPPED MUSSEL OIL                | A        |  |
| 2437                                     | GREEN S                                | E        | Only for use as a colour in topical and oral medicines.  |

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| <b>Item</b>                                     | <b>Ingredient name</b> | <b>Purpose</b>  | <b>Specific requirements</b>   |
| 2438  | GRIFOLA FRONDOSA       | A               | When the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label:<br><br>-(WARF) 'Do not take while on warfarin therapy without medical advice.'  |
| 2439  | GRINDELIA CAMPORUM     | A, H            |  |
| 2440  | GRINDELIA ROBUSTA      | A, H            |  |
| 2441  | GRISALVA               | 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%.  |
| 2442  | GROUND IVY HERB DRY    | A, H            |  |
| 2443  | GROUND IVY HERB POWDER | A, H            |  |
| 2444  | GUAIAAC WOOD 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 medicine must be no more 1%. |

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| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
| 2445                                     | GUAIACOL            | 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 the medicine must be no more than 5%.   |
| 2446                                     | GUAIACUM OFFICINALE | A, E, H  |   |
| 2447                                     | GUAIACUM RESIN      | A, E, H  |   |
| 2448                                     | GUAIACUM SANCTUM    | A, H     |   |
| 2449                                     | GUAIACWOOD ACETATE  | 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 than 1%. |
| 2450                                     | GUAIENE             | 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%.   |
| 2451                                     | GUAIYL ACETATE      | E        | Permitted for use only in combination with other permitted ingredients as a   |

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| Column 1                                 | Column 2           | Column 3 | Column 4  |
| Item                                     | Ingredient name    | Purpose  | Specific requirements   |
|  |                    |          | <p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>  |
| 2452                                     | GUANINE            | E        | Only for use as an excipient in topical medicines for dermal application.   |
| 2453                                     | GUANOSINE          | E        | <p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration must be no more than 0.01% in the medicine.</p>   |
| 2454                                     | GUAR GALACTOMANNAN | A        | <p>When for oral use:</p> <p>(a) the maximum daily dose must provide no more than 25 g of guar galactomannan;</p> <p>(b) the medicine requires the following dosage instructions:<br/>- (FIBRE) 'The dose of fibre should be increased gradually. Fluid intake should be increased with an increasing dose of fibre.' (or words to that effect)</p> <p>(c) when the dosage form is a powder preparation, the medicine requires the following dosage instructions:<br/>- (DNTPOW) 'Do not take powder alone. Mix with food</p> |

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| Item                                     | Ingredient name                            | Purpose  | Specific requirements   |
|  |  |          | or fluid.' (or words to that effect).   |
| 2455                                     | GUAR GUM                                   | A, E, H  |   |
| 2456                                     | GUAR<br>HYDROXYPROPYLTRIMONIUM<br>CHLORIDE | E        | Only for use as an excipient in topical medicines for dermal application.   |
| 2457                                     | GUAREA RUSBYI                              | A, H     |   |
| 2458                                     | GUAVA                                      | E        |   |
| 2459                                     | GURJUN BALSAM                              | 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%. |
| 2460                                     | GYMNADENIA NIGRA                           | A        |   |
| 2461                                     | GYMNEMA SYLVESTRE                          | A, H     |   |
| 2462                                     | GYMNOCLADUS DIOICA                         | A, H     |   |
| 2463                                     | GYNOSTEMMA<br>PENTAPHYLLUM                 | A        | The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).  |
| 2464                                     | GYNURA JAPONICA                            | A, H     |   |
| 2465                                     | HAHNEMANN'S SOLUBLE<br>MERCURY             | H        | Only for use as an active homoeopathic ingredient.  |
| 2466                                     | HALIBUT-LIVER OIL                          | A, E     | Colecalciferol and Vitamin A are mandatory components of Halibut-liver oil.   |

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| Item                                     | Ingredient name | Purpose  | Specific requirements   |
|  |                 |          | <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>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:</p> <ul style="list-style-type: none"> <li>- (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.</li> <li>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</li> <li>- (VITA3) ‘The recommended daily amount of Vitamin A</li> </ul> |

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| Item                                     | Ingredient name               | Purpose  | Specific requirements   |
|  |                               |          | from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’ |
| 2467                                     | HAMAMELIS LEAF DRY            | A, H     |   |
| 2468                                     | HAMAMELIS LEAF POWDER         | A, H     |   |
| 2469                                     | HAMAMELIS VIRGINIANA          | A, E, H  |   |
| 2470                                     | HAMAMELIS WATER               | A, E, H  |   |
| 2471                                     | HANDROANTHUS<br>HEPTAPHYLLUS  | A, H     |   |
| 2472                                     | HANDROANTHUS<br>IMPETIGINOSUS | A, E, H  |   |
| 2473                                     | HARD FAT                      | E        |   |
| 2474                                     | HARD PARAFFIN                 | E        |   |
| 2475                                     | HARICOT BEAN                  | E        |   |
| 2476                                     | HARPAGOPHYTUM<br>PROCUMBENS   | A, E, H  |   |
| 2477                                     | HARUNGANA<br>MADAGASCARIENSIS | A, H     |   |
| 2478                                     | HAZEL NUT                     | E        |   |
| 2479                                     | HAZEL NUT OIL                 | E        |   |
| 2480                                     | HEAVY KAOLIN                  | E        |   |
| 2481                                     | HEAVY MAGNESIUM OXIDE         | A, E, H  |   |
| 2482                                     | HECTORITE                     | E        | Only for use in topical medicines for dermal application.   |
| 2483                                     | HEDEOMA PULEGIOIDES           | A        |   |

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| 2484                                     | HEDERA HELIX                 | A, H     | Emetine is a mandatory component of Hedera helix.<br>The concentration of emetine in the medicine must be no more than 0.2%.  |
| 2485                                     | HEDTA                        | E        | Only for use as an excipient in topical medicines for dermal application.   |
| 2486                                     | HEKLA LAVA                   | H        | Only for use as an active homoeopathic ingredient.  |
| 2487                                     | HELESTRALIS                  | 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%. |
| 2488                                     | HELIANTHEMUM<br>NUMMULARIUM  | A, H     |   |
| 2489                                     | HELIANTHUS ANNUUS            | A, E, H  |   |
| 2490                                     | HELIANTHUS TUBEROSUS         | A, H     |   |
| 2491                                     | HELICHRYSUM<br>ANGUSTIFOLIUM | A, E, H  |   |
| 2492                                     | HELICHRYSUM ARENARIUM        | A, H     |   |
| 2493                                     | HELIOTROPYL ACETATE          | E        | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total  |

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| Item                                     | Ingredient name          | Purpose  | Specific requirements  |
|  |                          |          | fragrance concentration in a medicine must be no more than 1%.   |
| 2494                                     | HELLEBORUS NIGER         | A, H     | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.   |
| 2495                                     | HELLEBORUS VIRIDIS       | A, H     | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.   |
| 2496                                     | HELONIAS RHIZOME DRY     | A, H     |  |
| 2497                                     | HELONIAS RHIZOME POWDER  | A, H     |  |
| 2498                                     | HEMIDESMUS INDICUS       | A, E, H  |  |
| 2499                                     | HEPTANAL                 | 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%. |
| 2500                                     | HEPTANAL DIMETHYL ACETAL | 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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| Item                                     | Ingredient name | Purpose  | Specific requirements   |
| 2501                                     | HEPTANOIC ACID  | 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> |
| 2502                                     | HEPTENAL        | 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>  |
| 2503                                     | HEPTYL ACETATE  | 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>  |
| 2504                                     | HEPTYL BUTYRATE | 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</p>  |

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| Item                                     | Ingredient name                          | Purpose  | Specific requirements   |
|  |  |          | medicine must be no more than 5%.   |
| 2505                                     | HEPTYL UNDECYLENATE                      | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.<br>The concentration of the medicine must be no more than 25%. |
| 2506                                     | HERACLEUM HEMSLEYANUM                    | A, H     |   |
| 2507                                     | HERNIARIA GLABRA                         | A, H     |   |
| 2508                                     | HESPERIDIN                               | A, E     |   |
| 2509                                     | HEX-3-ENYL 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%.                           |
| 2510                                     | HEXAHYDRO-4,7-METHANOINDEN-6-YL PIVALATE | 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%.                           |
| 2511                                     | HEXAMETHYLINDANOPYRAN                    | E        | Permitted for use only in combination with other permitted ingredients as a   |

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| Column 1                                 | Column 2        | Column 3 | Column 4   |
| Item                                     | Ingredient name | Purpose  | Specific requirements  |
|  |                 |          | 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%.   |
| 2512                                     | HEXAN-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 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2513                                     | HEXANE          | E        | The concentration of the medicine must be no more than 0.029%.<br>When used for a route of administration other than topical, the residual solvent limit for Hexane is 2.9 mg per recommended daily dose.  |
| 2514                                     | HEXANOATE       | 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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| Item                                     | Ingredient name   | Purpose  | Specific requirements  |
|  |                   |          | 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 2515                                     | HEXANOIC ACID     | 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%. |
| 2516                                     | HEXASODIUM FYTATE | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.<br>The concentration of Hexasodium fytate in the medicine must be no more than 1.0 %.   |
| 2517                                     | HEXENAL           | 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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| Item                                     | Ingredient name        | Purpose  | Specific requirements  |
| 2518                                     | HEXYL 2-METHYLBUTYRATE | 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%.  |
| 2519                                     | HEXYL ACETATE          | 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%. |
| 2520                                     | HEXYL BUTYRATE         | 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%. |
| 2521                                     | HEXYL CAPROATE         | E        | Permitted for use only in combination with other permitted ingredients as a flavour.   |

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| Column 1                                 | Column 2          | Column 3 | Column 4  |
| Item                                     | Ingredient name   | Purpose  | Specific requirements   |
|  |                   |          | If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 2522                                     | HEXYL FORMATE     | 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%.       |
| 2523                                     | HEXYL ISOBUTYRATE | 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%. |
| 2524                                     | HEXYL ISOVALERATE | 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%. |
| 2525                                     | HEXYL LAURATE     | E        | Only for use as an excipient in topical medicines for dermal application.   |
| 2526                                     | HEXYL NICOTINATE  | E        |   |

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| Column 1                                 | Column 2         | Column 3 | Column 4  |
| Item                                     | Ingredient name  | Purpose  | Specific requirements   |
| 2527                                     | HEXYL PROPIONATE | E        | <p>Only for use in medicines 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> |
| 2528                                     | HEXYL SALICYLATE | 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>                                |
| 2529                                     | HEXYL TIGLATE    | 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>                                |
| 2530                                     | HEXYLDECANOL     | E        | <p>Only for use as an excipient in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration of the medicine must be no more than 3%.</p>          |

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| Column 1                                 | Column 2               | Column 3 | Column 4  |
| Item                                     | Ingredient name        | Purpose  | Specific requirements   |
| 2531                                     | HEXYLENE GLYCOL        | E        | Only for use as an excipient in topical medicines for dermal application.   |
| 2532                                     | HEXYLRESORCINOL        | A        | Permitted for use only in medicated throat lozenges.<br>The medicine of must not contain more than 2.5 mg of hexylresorcinol per lozenge.<br>The maximum recommended daily dose of the medicine must not provide more than 30mg of hexylresorcinol.<br>The medicine label must specify that the medicine is only to be used for 7 days (or less).<br>The following warning statement must be included on the medicine label:<br>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect). |
| 2533                                     | HIBISCUS ESCULENTUS    | A, H     |   |
| 2534                                     | HIBISCUS MUTABILIS     | A, H     |   |
| 2535                                     | HIBISCUS ROSA-SINENSIS | 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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| Item                                     | Ingredient name           | Purpose  | Specific requirements   |
| 2536                                     | HIBISCUS SABDARIFFA       | A, E, H  |   |
| 2537                                     | HIERACIUM PILOSELLA       | A, H     |   |
| 2538                                     | HIGH AMYLOSE MAIZE STARCH | A, E, H  |   |
| 2539                                     | HIGH CHROMIUM YEAST       | A, E     | Chromium is a mandatory component of high chromium yeast.<br>The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic chromium sources.<br>High chromium yeast is considered to be an organic form of chromium. |
| 2540                                     | HIGH FRUCTOSE MAIZE SYRUP | 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%.   |
| 2541                                     | HIGH MOLYBDENUM YEAST     | A, E     | Molybdenum is a mandatory component of high molybdenum yeast.<br>The maximum daily dose of molybdenum from high molybdenum yeast must be no more than 62.5 micrograms.  |
| 2542                                     | HIGH SELENIUM YEAST       | A        | When for oral or sublingual use, selenium is a mandatory component of high selenium   |

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| Column 1                                 | Column 2                     | Column 3 | Column 4  |
| Item                                     | Ingredient name              | Purpose  | Specific requirements   |
|  |                              |          | yeast.<br>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.<br>When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.' |
| 2543                                     | HIMATANTHUS LANCIFOLIUS      | A, E, H  |   |
| 2544                                     | HIPPOPHAE RHAMNOIDES         | A, E, H  |   |
| 2545                                     | HIRSCHFELDIA INCANA          | A, H     | Allyl isothiocyanate is a mandatory component of <i>Hirschfeldia incana</i> when the plant part is seed.<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%.   |
| 2546                                     | HISTAMINE<br>DIHYDROCHLORIDE | H        | Only for use as an active homoeopathic ingredient.  |
| 2547                                     | HISTIDINE                    | A        |   |
| 2548                                     | HISTIDINE HYDROCHLORIDE      | A, E, H  |   |
| 2549                                     | HO LEAF OIL                  | E        | Permitted for use only in combination with other permitted ingredients as a   |

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| Column 1                                 | Column 2                 | Column 3 | Column 4   |
| Item                                     | Ingredient name          | Purpose  | Specific requirements  |
|  |                          |          | 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%.   |
| 2550                                     | HO WOOD 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%. |
| 2551                                     | HOLCUS LANATUS           | A, H     |  |
| 2552                                     | HOLY THISTLE HERB DRY    | A, H     |  |
| 2553                                     | HOLY THISTLE HERB POWDER | A, H     |  |
| 2554                                     | HOMALOMENA OCCULTA       | A, H     |  |
| 2555                                     | HOMOSALATE               | A, E     | For use as an active ingredient only in sunscreens for dermal application.<br>For use as an excipient only in topical medicines for dermal application.<br>Not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more                    |

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| Item                                     | Ingredient name | Purpose  | Specific requirements   |
|  |                 |          | <p>than 15%.</p> <p>When used in primary 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>  |
| 2556                                     | HONEY           | A, E     | <p>When the route of administration is oral, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>- (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.</li> </ul> <p>If one of the sugars is lactose</p> |

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| Item                                     | Ingredient name | Purpose  | Specific requirements   |
|  |                 |          | then the medicine also requires the following warning statement on the medicine label:<br>- (LACT) 'Contains lactose' (or words to that effect).  |
| 2557                                     | HONEY BEE       | H        | Only for use as an active homoeopathic ingredient.  |
| 2558                                     | HONEY EXTRACT   | E        | Not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 1%.<br>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. |
| 2559                                     | HONEY POWDER    | E        | Permitted for use only in combination with other permitted ingredients as a flavour.  |

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| Column 1                                 | Column 2            | Column 3 | Column 4  |
| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
|  |                     |          | If used in a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 2560                                     | HOP STROBILE DRY    | A, H     |   |
| 2561                                     | HOP STROBILE POWDER | A, H     |   |
| 2562                                     | HOPS OIL            | A, E, H  |   |
| 2563                                     | HORDEUM DISTICHON   | A, E, H  | Gluten is a mandatory component when the plant part is seed, and must be declared in the application when the route of administration is other than topical and mucosal.            |
| 2564                                     | HORDEUM VULGARE     | A, E, H  | Gluten is a mandatory component when the plant part is seed, and must be declared in the application when the route of administration is other than topical and mucosal.            |
| 2565                                     | HOREHOUND EXTRACT   | 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%. |
| 2566                                     | HORSE RADISH        | E, H     | Volatile oil components (of <i>Armoracia rusticana</i> ) is a mandatory component of Horse radish.<br>The maximum recommended   |

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| Column 1                                 | Column 2                     | Column 3 | Column 4  |
| Item                                     | Ingredient name              | Purpose  | Specific requirements   |
|  |                              |          | daily dose must be no more than 20 mg of volatile oil components (of <i>Armoracia rusticana</i> ).  |
| 2567                                     | HOTTONIA PALUSTRIS           | A, H     |   |
| 2568                                     | HOUTTUYNIA CORDATA           | A, H     |   |
| 2569                                     | HOVENIA DULCIS               | A, H     |   |
| 2570                                     | HUMULUS LUPULUS              | A, E, H  |   |
| 2571                                     | HYALURONIC ACID              | E        | Only for use as an excipient in topical medicines for dermal application.   |
| 2572                                     | HYDNOCARPUS<br>ANTHELMINTICA | A, H     | When the medicine is for other than topical use and the plant part is seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry seed. |
| 2573                                     | HYDRANGAEA ARBORESCENS       | A, H     |   |
| 2574                                     | HYDRANGAEA PANICULATA        | A, H     |   |
| 2575                                     | HYDRASTIS CANADENSIS         | A, E, H  |   |
| 2576                                     | HYDRATED SILICA              | E        | Only for use when the route of administration is other than inhalation.   |
| 2577                                     | HYDROCHLORIC ACID            | E        | The concentration of the medicine must be no more than 0.5%.  |
| 2578                                     | HYDROCOTYLE UMBELLATA        | A, H     |   |

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| Item                                     | Ingredient name                                  | Purpose  | Specific requirements   |
| 2579                                     | HYDROFLUORIC ACID                                | H        | Only for use as an active homoeopathic ingredient.  |
| 2580                                     | HYDROGEN CYANIDE                                 | H        | Only for use as an active homoeopathic ingredient.  |
| 2581                                     | HYDROGEN PEROXIDE                                | A, E     | <p>When used as the active ingredient, it is only for use in topical medicines for dermal application.</p> <p>The concentration of hydrogen peroxide in the medicine must be no more than 3%.</p> <p>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.</p> |
| 2582                                     | HYDROGENATED BUTYLENE/ETHYLENE/STYRENE COPOLYMER | E        | <p>Only for use in topical medicines for dermal application.</p> <p>The combined concentration of hydrogenated butylene/ethylene/styrene copolymer and hydrogenated ethylene/propylene/styrene copolymer in the medicine must be no more than 9%.</p>   |
| 2583                                     | HYDROGENATED C6-14 OLEFIN POLYMERS               | E        | Only for use in topical medicines for dermal application and not to be  |

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| Column 1                                 | Column 2  | Column 3 | Column 4   |
| Item                                     | Ingredient name                                     | Purpose  | Specific requirements  |
|  |   |          | included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 7%.   |
| 2584                                     | HYDROGENATED CASTOR OIL                             | E        |  |
| 2585                                     | HYDROGENATED COCO-GLYCERIDES                        | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 3%.                |
| 2586                                     | HYDROGENATED COCONUT OIL                            | E        |  |
| 2587                                     | HYDROGENATED COTTONSEED OIL                         | E        |  |
| 2588                                     | HYDROGENATED DILINOLEYL/DIMETHYLCARBONATE COPOLYMER | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 4% in the product. |
| 2589                                     | HYDROGENATED ETHYLENE/PROPYLENE/STYRENE COPOLYMER   | E        | The combined concentration of hydrogenated ethylene/propylene/styrene copolymer must be no more than 9%.   |

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| Column 1                                 | Column 2                             | Column 3 | Column 4   |
| Item                                     | Ingredient name                      | Purpose  | Specific requirements  |
| 2590                                     | HYDROGENATED LANOLIN                 | E        |  |
| 2591                                     | HYDROGENATED LECITHIN                | 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%.              |
| 2592                                     | HYDROGENATED PALM GLYCERIDES         | 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 1.6%.            |
| 2593                                     | HYDROGENATED PALM GLYCERIDES CITRATE | 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 0.01%. |
| 2594                                     | HYDROGENATED PALM KERNEL OIL         | 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 1.2%.            |

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| Column 1                                 | Column 2                  | Column 3 | Column 4  |
| Item                                     | Ingredient name           | Purpose  | Specific requirements   |
| 2595                                     | HYDROGENATED PALM OIL     | 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 2%.</p> <p>Polycyclic aromatic hydrocarbons must be kept below the level of detection.</p>   |
| 2596                                     | HYDROGENATED POLYDECENE   | 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>  |
| 2597                                     | HYDROGENATED POLYDEXTROSE | A        | <p>Only to be used in a medicine where Danisco Australia Pty Ltd (Client ID 54247), 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 2 March 2022.</p> <p>Only permitted for use in medicines:</p> <ul style="list-style-type: none"> <li>- limited to oral routes of administration; and</li> <li>- when the maximum recommended daily dose does not provide more than 15g of</li> </ul> |

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| Item                                     | Ingredient name                                    | Purpose  | Specific requirements   |
|  |  |          | hydrogenated polydextrose.  |
| 2598                                     | HYDROGENATED POLYISOBUTENE                         | E        | Only for use in topical medicines for dermal application.   |
| 2599                                     | HYDROGENATED SOYA OIL                              | E        |   |
| 2600                                     | HYDROGENATED TALLOW GLYCERIDE                      | 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%.           |
| 2601                                     | HYDROGENATED VEGETABLE OIL                         | E        |   |
| 2602                                     | HYDROLIAC  | 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%.               |
| 2603                                     | HYDROLYSED ADANSONIA DIGITATA LEAF POLYSACCHARIDES | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.01% |

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| Column 1                                 | Column 2                      | Column 3 | Column 4  |
| Item                                     | Ingredient name               | Purpose  | Specific requirements   |
| 2604                                     | HYDROLYSED ALGIN              | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br><br>The concentration in the medicine must be no more than 0.02% |
| 2605                                     | HYDROLYSED CEREAL SOLIDS      | 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%.               |
| 2606                                     | HYDROLYSED COLLAGEN           | A, E     |   |
| 2607                                     | HYDROLYSED ELASTIN            | E        | Only for use in topical medicines for dermal application.   |
| 2608                                     | HYDROLYSED GELATIN            | A, E     |   |
| 2609                                     | HYDROLYSED GLYCOSAMINOGLYCANS | E        | Only for use in topical medicines for dermal application.   |
| 2610                                     | HYDROLYSED JOJOBA ESTERS      | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br><br>The concentration in the medicine must be no more than 5%.   |

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| Item                                     | Ingredient name              | Purpose  | Specific requirements   |
| 2611                                     | HYDROLYSED 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%.             |
| 2612                                     | HYDROLYSED MAIZE STARCH      | E        |   |
| 2613                                     | HYDROLYSED MILK PROTEIN      | E        |   |
| 2614                                     | HYDROLYSED RICE              | A, E, H  |   |
| 2615                                     | HYDROLYSED RICE PROTEIN      | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.125%. |
| 2616                                     | HYDROLYSED SOY PROTEIN       | E        | Only for use in topical medicines for dermal application not to be included in topical medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.5%.       |
| 2617                                     | HYDROLYSED VEGETABLE PROTEIN | E        |   |
| 2618                                     | HYDROLYSED WHEAT PROTEIN     | E        | Gluten is a mandatory component of hydrolysed wheat protein.  |

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| Item                                     | Ingredient name                              | Purpose  | Specific requirements  |
| 2619                                     | HYDROLYSED WHEAT<br>PROTEIN/PVP CROSSPOLYMER | E        | Only for use in topical<br>medicines for dermal<br>application and not to be<br>included in topical medicines<br>intended for use in the eye.<br><br>The concentration in the<br>medicine must be no more than<br>1.2%.  |
| 2620                                     | HYDROLYSED YEAST PROTEIN                     | E        | Only for use in topical<br>medicines for dermal<br>application and not to be<br>included in topical medicines<br>intended for use in the eye or<br>on damaged skin.<br><br>The concentration in the<br>medicine must be no more than<br>0.3%.  |
| 2621                                     | HYDROQUINONE DIMETHYL<br>ETHER               | E        | Permitted for use only in<br>combination with other<br>permitted ingredients as a<br>flavour or a fragrance.<br><br>If used in a flavour the total<br>flavour concentration in a<br>medicine must be no more than<br>5%.<br><br>If used in a fragrance the total<br>fragrance concentration in a<br>medicine must be no more 1%. |
| 2622                                     | HYDROUS WOOL FAT                             | A, E     | When used as an active<br>ingredient, can only be<br>supplied as an uncompounded<br>medicine substance packed for<br>retail sale, and must comply  |

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| Item                                     | Ingredient name        | Purpose  | Specific requirements  |
|  |                        |          | with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.  |
| 2623                                     | HYDROXOCOBALAMIN       | A        |  |
| 2624                                     | HYDROXYACETOPHENONE    | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.<br><br>The concentration in the medicine must be no more than 1%.   |
| 2625                                     | HYDROXYAPATITE         | A, E     |  |
| 2626                                     | HYDROXYCITRATE COMPLEX | A        | Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.  |
| 2627                                     | HYDROXYCITRIC ACID     | A        |  |
| 2628                                     | HYDROXYCITRONELLAL     | 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%. |

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| Column 1                                 | Column 2   | Column 3 | Column 4   |
| Item                                     | Ingredient name  | Purpose  | Specific requirements  |
| 2629                                     | HYDROXYCITRONELLAL<br>DIMETHYL ACETAL                  | 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%. |
| 2630                                     | HYDROXYCITRONELLAL-<br>METHYLANTHRANILATE              | 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%. |
| 2631                                     | HYDROXYCITRONELLOL                                     | 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%.  |
| 2632                                     | HYDROXYETHYL<br>CETEARAMIDOPROPYLDIMONI<br>UM CHLORIDE | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines   |

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| Column 1                                 | Column 2                           | Column 3 | Column 4   |
| Item                                     | Ingredient name                    | Purpose  | Specific requirements  |
|  |                                    |          | intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%.   |
| 2633                                     | HYDROXYETHYL UREA                  | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration must be no more than 1%.                      |
| 2634                                     | HYDROXYLATED LANOLIN               | E        |  |
| 2635                                     | HYDROXYLATED MILK GLYCERIDES       | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration must be no more than 0.1%.                    |
| 2636                                     | HYDROXYLYSINE                      | A, E     |  |
| 2637                                     | HYDROXYMETHYLCELLULOSE             | E        |  |
| 2638                                     | HYDROXYOCTACOSANYL HYDROXYSTEARATE | E        | Only for use in topical medicines for dermal application.  |
| 2639                                     | HYDROXYPALMITOYL SPHINGANINE       | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.<br>The concentration must be no more than 0.1%. |

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| Column 1                                 | Column 2                         | Column 3 | Column 4   |
| Item                                     | Ingredient name                  | Purpose  | Specific requirements  |
| 2640                                     | HYDROXYPROLINE                   | A, E     |  |
| 2641                                     | HYDROXYPROPYL DISTARCH PHOSPHATE | E        | <p>Only permitted for:</p> <ul style="list-style-type: none"> <li>- use in topical medicines for dermal application; and</li> <li>- medicines for internal use.</li> </ul> <p>When for use in topical medicines for dermal application:</p> <ul style="list-style-type: none"> <li>- not to be included medicines intended for use in the eye or damaged skin; and</li> <li>- the concentration of hydroxypropyl distarch phosphate in the medicine must be no more than 4%.</li> </ul> <p>When for internal use, the maximum recommended daily dose must not contain more than 240mg of hydroxypropyl distarch phosphate.</p> |
| 2642                                     | HYDROXYPROPYL STARCH             | E        |  |
| 2643                                     | HYDROXYPROPYLBETADEX             | E        | Only for use in topical medicines for dermal application.  |
| 2644                                     | HYDROXYSTEARIC ACID              | E        | <p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration must be no more than 9%.</p>   |

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| Item                                     | Ingredient name        | Purpose  | Specific requirements  |
| 2645                                     | HYETELLOSE             | E        |  |
| 2646                                     | HYLOCEREUS LEMAIREI    | E        | Permitted for use only as a colour for oral and topical use.   |
| 2647                                     | HYLOCEREUS UNDATUS     | A, H     |  |
| 2648                                     | HYMETELLOSE            | E        |  |
| 2649                                     | HYOSCYAMUS LEAF DRY    | A, H     | Alkaloids calculated as hyoscyamine and hyoscyamine are mandatory components of Hyoscamus leaf dry.<br>The concentration of alkaloids calculated as hyoscyamine 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 than 300 micrograms/kg or 300 micrograms/L or 0.00003%. |
| 2650                                     | HYOSCYAMUS LEAF POWDER | A, H     | Alkaloids calculated as hyoscyamine and hyoscyamine are mandatory components of Hyoscamus leaf powder.<br>The concentration of alkaloids calculated as hyoscyamine 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%.   |

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| Item                                     | Ingredient name        | Purpose  | Specific requirements   |
| 2651                                     | HYOSCYAMUS NIGER       | A, H     | Alkaloids calculated as hyoscyamine and hyoscyne are mandatory components of <i>Hyoscyamus niger</i> .<br>The concentration of hyoscyamine in the medicine must be no more than 3 micrograms/kg or 3 micrograms/L or 0.3%.<br>The concentration of hyoscyne in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%. |
| 2652                                     | HYPERICUM ASCYRON      | A, H     |   |
| 2653                                     | HYPERICUM JAPONICUM    | A, H     |   |
| 2654                                     | HYPERICUM PERFORATUM   | A, E, H  | When used for oral ingestion, the medicine requires the following warning statement on the medicine label:<br>- (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'  |
| 2655                                     | HYPROLOSE              | E        |   |
| 2656                                     | HYPROMELLOSE           | E        |   |
| 2657                                     | HYPROMELLOSE PHTHALATE | E        |   |
| 2658                                     | HYPTIS SUAVEOLENS      | A, H     |   |
| 2659                                     | HYSSOPUS OFFICINALIS   | A, E, H  |   |
| 2660                                     | IBERIS AMARA           | A, H     |   |
| 2661                                     | ICHTHAMMOL             | H        | Only for use as an active   |

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| Column 1                                 | Column 2            | Column 3 | Column 4  |
| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
|  |                     |          | homoeopathic ingredient.  |
| 2662                                     | ILEX AQUIFOLIUM     | A, H     |   |
| 2663                                     | ILEX CHINENSIS      | A, H     |   |
| 2664                                     | ILEX PARAGUARIENSIS | A, E, H  | <p>Caffeine is a mandatory component of Ilex paraguariensis.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 September 2019; or</li> <li>- is supplied after 2 March 2021.</li> </ul> <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> <li>- was listed in the Register before 2 September 2019; and</li> <li>- is supplied before 2 March 2021;</li> </ul> <p>may comply with the requirements in paragraphs (a)</p> |

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| Item                                     | Ingredient name | Purpose  | Specific requirements   |
|  |                 |          | <p>to (e) below.</p> <p>a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.</p> <p>b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect).</li> <li>- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'</li> <li>- (CAFFPREG) 'Caffeine</li> </ul> |

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|  |                   |          | <p>intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’</p> <p>e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</li> <li>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</li> </ul> |
| 2665                                     | ILEX ROTUNDA      | A, H     |   |
| 2666                                     | ILEX VERTICILLATA | A, H     |   |
| 2667                                     | ILLICIAM VERUM    | A, H     | <p>When the plant preparation is oil or distillate, and the concentration of Illicium verum oil or distillate in the preparation is greater than 50%:</p> <ul style="list-style-type: none"> <li>(a) the nominal capacity of the container must not be more than 50 millilitres;</li> <li>(b) a restricted flow insert must be fitted on the container; and</li> <li>(c) the following warning statement is required on the label:</li> </ul> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach</li> </ul>  |

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| Column 1                                 | Column 2        | Column 3 | Column 4  |
| Item                                     | Ingredient name | Purpose  | Specific requirements   |
|  |                 |          | of children' (or words to that effect).   |
| 2668                                     | IMIDUREA        | E        | Only for use in topical medicines for dermal application.   |
| 2669                                     | IMMORTELLE      | 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%. |
| 2670                                     | IMMORTELLE OIL  | 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%. |
| 2671                                     | IMPATIENS       | 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%.   |
| 2672                                     | IMPATIENS BALSAMINA           | A, H     |   |
| 2673                                     | IMPATIENS GLANDULIFERA        | A, H     |   |
| 2674                                     | IMPERATA CYLINDRICA           | A, E, H  |   |
| 2675                                     | INDIGO CARMINE                | E        | Permitted for use only as a colour in medicines limited to topical and oral routes of administration.   |
| 2676                                     | INDIGO CARMINE ALUMINIUM LAKE | E        | Permitted for use only as a colour in medicines limited to topical and oral routes of administration.   |
| 2677                                     | INDIGOFERA TINCTORIA          | A, H     |   |
| 2678                                     | INDISAN                       | 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%. |
| 2679                                     | INDOLE                        | E, H     | Only for use as an active homoeopathic or excipient ingredient.<br>The maximum recommended daily dose must contain no more than 75 mg indole.   |
| 2680                                     | INDOLENE                      | E        | Permitted for use only in combination with other permitted ingredients as a fragrance.  |

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| Item                                     | Ingredient name              | Purpose  | Specific requirements   |
|  |                              |          | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.   |
| 2681                                     | INDUSTRIAL METHYLATED SPIRIT | E        |   |
| 2682                                     | INOSITOL                     | A, E     |   |
| 2683                                     | INULA BRITANNICA             | A, H     |   |
| 2684                                     | INULA HELENIUM               | A, E, H  |   |
| 2685                                     | INULA RACEMOSA               | A, H     |   |
| 2686                                     | INULIN                       | A, E     |   |
| 2687                                     | INULIN LAURYL CARBAMATE      | 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 1.2%.   |
| 2688                                     | INVERT SUGAR                 | E        | When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:<br>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR<br>'Contains sugars' (or words to |

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|  |                 |          | that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:<br>- (LACT) 'Contains lactose' (or words to that effect).   |
| 2689                                     | INVERT SYRUP    | E        | Glucose is a mandatory component of Invert syrup when the route of administration is oral or sublingual.<br><br>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:<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>- (LACT) 'Contains lactose' (or words to that effect). |

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| 2690                                     | IODINE                         | H        | <p>Only for use as an active homoeopathic ingredient.</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>                        |
| 2691                                     | IODOPROPYNYL<br>BUTYLCARBAMATE | E        | <p>For use as an excipient ingredient in topical medicines only.</p> <p>The concentration in aqueous medicines must be no more than 10%.</p>  |
| 2692                                     | IONONE                         | E        | <p>Permitted for use only:</p> <p>(a) in topical medicines for dermal application; and</p> <p>(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> |
| 2693                                     | IOPAMIDOL                      | E        | Permitted for use only in combination with other  |

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| Item                                     | Ingredient name                 | Purpose  | Specific requirements   |
|  |                                 |          | permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.              |
| 2694                                     | IPECACUANHA DRY                 | A, H     | Emetine is a mandatory component of Ipecacuanha Dry.<br>The concentration of emetine in the medicine must be no more than 0.2%.                 |
| 2695                                     | IPECACUANHA POWDER              | A, H     | Emetine is a mandatory component of Ipecacuanha Powder.<br>The concentration of emetine in the medicine must be no more than 0.2%.              |
| 2696                                     | IPECACUANHA PREPARED            | A, H     | Emetine is a mandatory component of Ipecacuanha Prepared.<br>The concentration of emetine in the medicine must be no more than 0.2%.            |
| 2697                                     | IPECACUANHA ROOT LIQUID EXTRACT | A, H     | Emetine is a mandatory component of Ipecacuanha root liquid extract.<br>The concentration of emetine in the medicine must be no more than 0.2%. |
| 2698                                     | IPOMOEA BATATAS                 | A, H     |   |
| 2699                                     | IPOMOEA JALAPA                  | A, H     |   |

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| Item                                     | Ingredient name       | Purpose  | Specific requirements  |
| 2700                                     | IRIDOPHYCUS FLACCIDUM | A, H     | <p>Iodine is a mandatory component of Iridophycus flaccidum.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>  |
| 2701                                     | IRIS DOMESTICA        | A, H     |  |
| 2702                                     | IRIS FLORENTINA       | A, H     |  |
| 2703                                     | IRIS GERMANICA        | A, H     |  |
| 2704                                     | IRIS PALLIDA          | A, H     |  |
| 2705                                     | IRIS TENAX            | H        |  |
| 2706                                     | IRIS VERSICOLOR       | A, H     |  |
| 2707                                     | IRON                  | A, H     | <p>Only for use in oral medicines.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when</p> |

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|  |   |          | <p>present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |
| 2708                                     | IRON (II) BISGLYCINE SULFATE TRIHYDRATE | A        | <p>Only for use in oral medicines.</p> <p>Iron is a mandatory component of iron (II) bisglycine sulfate trihydrate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of</p>  |

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| Item                                     | Ingredient name     | Purpose  | Specific requirements  |
|  |                     |          | <p>iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |
| 2709                                     | IRON (II) GLYCINATE | A        | <p>Only for use in oral medicines.</p> <p>Iron is a mandatory component of iron (II) glycinate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of</p>  |

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|  |                      |          | <p>iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |
| 2710                                     | IRON (III) GLYCINATE | A        | <p>Only for use in oral medicines.</p> <p>Iron is a mandatory component of iron (III) glycinate.</p> <p>When for internal use, the</p>  |

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| Item                                     | Ingredient name | Purpose  | Specific requirements  |
|  |                 |          | <p>medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the</p> |

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| Item                                     | Ingredient name         | Purpose  | Specific requirements   |
|  |                         |          | treatment of iron deficiency conditions' (or words to that effect).   |
| 2711                                     | IRON AMINO ACID CHELATE | A, H     | <p>Only for use in oral medicines.</p> <p>When used internally, iron is a mandatory component of iron amino acid chelate.</p> <p>The concentration of iron in iron amino acid chelate must be no more than 25%.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are</p> |

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| Item                                     | Ingredient name  | Purpose  | Specific requirements   |
|  |                  |          | <p>required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>                              |
| 2712                                     | IRON OXIDE BLACK | E        | <p>Permitted for use only as a colour in medicines limited to topical and oral routes of administration.</p> <p>When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.</p> |
| 2713                                     | IRON OXIDE RED   | E        | <p>Permitted for use only as a colour in medicines limited to topical and oral routes of administration.</p> <p>When used in undivided</p>  |

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|--|-------------------|----------|---|
| Column 1                                 | Column 2          | Column 3 | Column 4  |
| Item                                     | Ingredient name   | Purpose  | Specific requirements   |
|  |                   |          | <p>preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.</p>   |
| 2714                                     | IRON OXIDE YELLOW | E        | <p>Permitted for use only as a colour in medicines limited to topical and oral routes of administration.</p> <p>When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.</p> |
| 2715                                     | IRON PHOSPHATE    | A, E, H  | <p>When used internally, iron is a mandatory component of iron phosphate and must be declared.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the</p>   |

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|--|--------------------------|----------|---|
| Column 1                                 | Column 2                 | Column 3 | Column 4  |
| Item                                     | Ingredient name          | Purpose  | Specific requirements   |
|  |                          |          | <p>primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> |
| 2716                                     | IRONE                    | E        |   |
| 2717                                     | IRVINGIA GABONENSIS SEED | E        | Only for use in topical medicines for dermal  |

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| Column 1                                 | Column 2                 | Column 3 | Column 4   |
| Item                                     | Ingredient name          | Purpose  | Specific requirements  |
|  | TRIGLYCERIDES            |          | application and not to be included in topical medicines intended for use in the eye.<br>The concentration must be no more than 0.375%.   |
| 2718                                     | ISATIS TINCTORIA         | A, H     |  |
| 2719                                     | ISOAMBRETTOLIDE          | 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%. |
| 2720                                     | ISOAMYL 2-METHYLBUTYRATE | 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%.  |
| 2721                                     | ISOAMYL 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                              |

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| Column 1                                 | Column 2         | Column 3 | Column 4   |
| Item                                     | Ingredient name  | Purpose  | Specific requirements  |
|  |                  |          | medicine must be no more 1%.   |
| 2722                                     | ISOAMYL 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%. |
| 2723                                     | ISOAMYL BENZOATE | 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%. |
| 2724                                     | ISOAMYL BUTYRATE | 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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| Column 1                                 | Column 2                   | Column 3 | Column 4  |
| Item                                     | Ingredient name            | Purpose  | Specific requirements   |
| 2725                                     | ISOAMYL CAPRYLATE          | 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> |
| 2726                                     | ISOAMYL CINNAMATE          | 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> |
| 2727                                     | ISOAMYL CITRONELLYL KETONE | 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>  |
| 2728                                     | ISOAMYL FORMATE            | E        | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p>  |

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|--|---------------------|----------|---|
| Column 1                                 | Column 2            | Column 3 | Column 4  |
| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
|  |                     |          | <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>  |
| 2729                                     | ISOAMYL HEXANOATE   | 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> |
| 2730                                     | ISOAMYL ISOBUTYRATE | 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> |
| 2731                                     | ISOAMYL ISOVALERATE | 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</p>  |

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| Column 1                                 | Column 2                 | Column 3 | Column 4  |
| Item                                     | Ingredient name          | Purpose  | Specific requirements   |
|  |                          |          | flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 2732                                     | ISOAMYL LAURATE          | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration must be no more than 12%.  |
| 2733                                     | ISOAMYL METHOXYCINNAMATE | A        | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.<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). |
| 2734                                     | ISOAMYL PHENYLACETATE    | E        | Permitted for use only in combination with other permitted ingredients as a   |

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| Column 1                                 | Column 2                     | Column 3 | Column 4   |
| Item                                     | Ingredient name              | Purpose  | Specific requirements  |
|  |                              |          | 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%.   |
| 2735                                     | ISOAMYL PHENYLETHYL<br>ETHER | 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%.   |
| 2736                                     | ISOAMYL 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 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%. |
| 2737                                     | ISOAMYL SALICYLATE           | 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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| Column 1                                 | Column 2          | Column 3 | Column 4  |
| Item                                     | Ingredient name   | Purpose  | Specific requirements   |
|  |                   |          | <p>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>  |
| 2738                                     | ISOBERGAMIATE     | 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>  |
| 2739                                     | ISOBORNEOL        | 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> |
| 2740                                     | ISOBORNYL ACETATE | 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> |

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| Column 1                                 | Column 2               | Column 3 | Column 4   |
| Item                                     | Ingredient name        | Purpose  | Specific requirements  |
| 2741                                     | ISOBORNYL CYCLOHEXANOL | 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%.  |
| 2742                                     | ISOBUTANE              | E        | Only for use in topical medicines for dermal application.  |
| 2743                                     | ISOBUTYL ACETATE       | 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%. |
| 2744                                     | ISOBUTYL ALCOHOL       | E        | The residual solvent limit for Isobutyl alcohol is 50mg per recommended daily dose.<br><br>The concentration of isobutyl alcohol must be no more than 0.5% of the formulation.   |
| 2745                                     | ISOBUTYL BENZOATE      | E        | Permitted for use only in combination with other permitted ingredients as a  |

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| Column 1                                 | Column 2                 | Column 3 | Column 4  |
| Item                                     | Ingredient name          | Purpose  | Specific requirements   |
|  |                          |          | flavour.<br>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.   |
| 2746                                     | ISOBUTYL BENZYL CARBINOL | E        | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2747                                     | ISOBUTYL 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%. |
| 2748                                     | ISOBUTYL 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%. |
| 2749                                     | ISOBUTYL CINNAMATE       | E        | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total  |

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| Column 1                                 | Column 2                 | Column 3 | Column 4   |
| Item                                     | Ingredient name          | Purpose  | Specific requirements  |
|  |                          |          | flavour concentration in a medicine must be no more than 5%.   |
| 2750                                     | ISOBUTYL FORMATE         | 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%.  |
| 2751                                     | ISOBUTYL HYDROXYBENZOATE | E        | Only for use in topical medicines for dermal application.<br><br>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:<br><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. |
| 2752                                     | ISOBUTYL ISOBUTYRATE     | 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   |

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| Column 1                                 | Column 2               | Column 3 | Column 4   |
| Item                                     | Ingredient name        | Purpose  | Specific requirements  |
|  |                        |          | 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.  |
| 2753                                     | ISOBUTYL 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%.  |
| 2754                                     | ISOBUTYL 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%. |
| 2755                                     | ISOBUTYL PROPIONATE    | 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%.  |
| 2756                                     | ISOBUTYL QUINOLINE     | E        | Permitted for use only in combination with other permitted ingredients as a  |

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| Column 1                                 | Column 2                       | Column 3 | Column 4  |
| Item                                     | Ingredient name                | Purpose  | Specific requirements   |
|  |                                |          | <p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>  |
| 2757                                     | ISOBUTYL SALICYLATE            | E        | Only for use in topical medicines for dermal application.   |
| 2758                                     | ISOBUTYLENE/ISOPRENE COPOLYMER | E        | <p>Only for oral use when the dosage form is chewing gum.</p> <p>The concentration must be consistent with best practice for the production of gum delivery systems.</p>  |
| 2759                                     | ISOBUTYRALDEHYDE               | 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>  |
| 2760                                     | ISOBUTYRIC ACID                | 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> |

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| Column 1                                 | Column 2                    | Column 3 | Column 4  |
| Item                                     | Ingredient name             | Purpose  | Specific requirements   |
| 2761                                     | ISOCETYL ALCOHOL            | E        | Only for use in topical medicines for dermal application.   |
| 2762                                     | ISOCETYL LINOLEOYL STEARATE | E        | Only for use in topical medicines for dermal application.   |
| 2763                                     | ISOCETYL STEARATE           | E        | Only for use in topical medicines for dermal application.   |
| 2764                                     | ISOCETYL STEAROYL STEARATE  | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration must be no more than 10%.          |
| 2765                                     | ISOCYCLOCITRAL              | 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%. |
| 2766                                     | ISODECYL ISONONANOATE       | E        | Only for use in topical medicines for dermal application.   |
| 2767                                     | ISODECYL NEOPENTANOATE      | E        | Only for use in topical medicines for dermal  |

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| Column 1                                 | Column 2            | Column 3 | Column 4  |
| Item                                     | Ingredient name     | Purpose  | Specific requirements   |
|  |                     |          | application.  |
| 2768                                     | ISODECYL OLEATE     | E        | Only for use in topical medicines for dermal application.   |
| 2769                                     | ISODECYL SALICYLATE | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration must be no more than 2%.   |
| 2770                                     | ISODODECANE         | E        | Only for use in topical medicines for dermal application.   |
| 2771                                     | ISOEICOSANE         | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration must be no more than 2%.   |
| 2772                                     | 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 |

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| Column 1                                 | Column 2                | Column 3 | Column 4   |
| Item                                     | Ingredient name         | Purpose  | Specific requirements  |
|  |                         |          | medicine must be no more 1%.   |
| 2773                                     | ISOEUGENYL 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%. |
| 2774                                     | ISOEUGENYL BENZYL ETHER | 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%.  |
| 2775                                     | ISOHEXADECANE           | E        | Only for use in topical medicines for dermal application.  |
| 2776                                     | ISOJASMONE              | E        | Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation.<br>The total flavour proprietary excipient formulation in a medicine must not be more than 5%.                             |

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| Column 1                                 | Column 2        | Column 3 | Column 4   |
| Item                                     | Ingredient name | Purpose  | Specific requirements  |
|  |                 |          | The total fragrance proprietary excipient formulation in a medicine must not be more 1%.   |
| 2777                                     | ISOLEUCINE      | A, E     |  |
| 2778                                     | ISOMALT         | 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]' |
| 2779                                     | ISOMENTHONE     | 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%.   |
| 2780                                     | ISOMETHYLIONONE | E        | Permitted for use only in combination with other permitted ingredients as a  |

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| Column 1                                 | Column 2              | Column 3 | Column 4   |
| Item                                     | Ingredient name       | Purpose  | Specific requirements  |
|  |                       |          | <p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>   |
| 2781                                     | ISONONYL 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>  |
| 2782                                     | ISONONYL ISONONANOATE | E        | <p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.</p> <p>The concentration must be no more than 15%.</p>   |
| 2783                                     | ISOPENTANE            | E        | <p>For dental use only.</p> <p>The concentration must be no more than 2%.</p>  |
| 2784                                     | ISOPENTANOIC ACID     | 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</p> |

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| Column 1                                 | Column 2                    | Column 3 | Column 4   |
| Item                                     | Ingredient name             | Purpose  | Specific requirements  |
|  |                             |          | medicine must be no more 1%.   |
| 2785                                     | ISOPHORONE                  | 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%.  |
| 2786                                     | ISOPHYTOL                   | 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%. |
| 2787                                     | ISOPROPYL 2-METHYLBUTYRATE  | 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%. |
| 2788                                     | ISOPROPYL 4-HYDROXYBENZOATE | E        | Only for use in topical medicines for dermal   |

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| Column 1                                 | Column 2            | Column 3 | Column 4   |
| Item                                     | Ingredient name     | Purpose  | Specific requirements  |
|  |                     |          | <p>application.</p> <p>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:</p> <p>- (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.</p> |
| 2789                                     | ISOPROPYL ACETATE   | E        | Only for use in topical medicines for dermal application.  |
| 2790                                     | ISOPROPYL ALCOHOL   | E        |  |
| 2791                                     | ISOPROPYL CAPROATE  | 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>   |
| 2792                                     | ISOPROPYL CINNAMATE | 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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| Permissible ingredients and requirements |   |          |   |
|--|---|----------|---|
| Column 1                                 | Column 2                                | Column 3 | Column 4  |
| Item                                     | Ingredient name                         | Purpose  | Specific requirements   |
| 2793                                     | ISOPROPYL ISOSTEARATE                   | E        | Only for use in topical medicines for dermal application.   |
| 2794                                     | ISOPROPYL LANOLATE                      | E        | Only for use in topical medicines for dermal application.   |
| 2795                                     | ISOPROPYL LAUROYL SARCOSINATE           | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration must be no more than 5.6%. |
| 2796                                     | ISOPROPYL MYRISTATE                     | E        |   |
| 2797                                     | ISOPROPYL PALMITATE                     | E        | Only for use in topical medicines for dermal application.   |
| 2798                                     | ISOPROPYL PPG-2 ISODECETH-7 CARBOXYLATE | E        | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration must be no more than 10%.  |
| 2799                                     | ISOPROPYL STEARATE                      | E        | Only for use in topical medicines for dermal application.   |
| 2800                                     | ISOPROPYL TITANIUM                      | E        | Only for use in topical   |

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|--|-----------------------------------|----------|--|
| Column 1                                 | Column 2                          | Column 3 | Column 4   |
| Item                                     | Ingredient name                   | Purpose  | Specific requirements  |
|  | TRIISOSTEARATE                    |          | medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration must be no more than 0.2%.  |
| 2801                                     | ISOPROPYL-3-METHYL-BUTANE THIOATE | 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%.  |
| 2802                                     | ISOPULEGOL                        | 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%. |
| 2803                                     | ISORALDEINE 70                    | 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%.  |
| 2804                                     | ISOSTEARIC ACID                   | E        | Only for use in topical  |

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|--|---------------------------------|----------|---|
| Column 1                                 | Column 2                        | Column 3 | Column 4  |
| Item                                     | Ingredient name                 | Purpose  | Specific requirements   |
|  |                                 |          | medicines for dermal application.   |
| 2805                                     | ISOSTEAROYL HYDROLYSED COLLAGEN | 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 must be no more than 0.3%.                 |
| 2806                                     | ISOSTEARYL ALCOHOL              | E        | Only for use in topical medicines for dermal application.   |
| 2807                                     | ISOSTEARYL NEOPENTANOATE        | E        | Only for use in topical medicines for dermal application.   |
| 2808                                     | ISOSTEARYL PALMITATE            | 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 must be no more than 2%.                   |
| 2809                                     | ISOTRIDECYL ALCOHOL             | 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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|--|--------------------|----------|---|
| Column 1                                 | Column 2           | Column 3 | Column 4  |
| Item                                     | Ingredient name    | Purpose  | Specific requirements   |
| 2810                                     | ISOVALERALDEHYDE   | 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>   |
| 2811                                     | ISOVALERIC ACID    | 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>   |
| 2812                                     | ISPAGHULA HUSK DRY | A, H     | <p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 March 2020; or</li> <li>- is supplied after 2 March 2021.</li> </ul> <p>(a) When a dose for children is stated, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> <li>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that</li> </ul> |

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| Column 1                                 | Column 2              | Column 3 | Column 4  |
| Item                                     | Ingredient name       | Purpose  | Specific requirements   |
|  |                       |          | <p>effect).</p> <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register before 2 March 2020; and</li> <li>- is supplied before 2 March 2021; and</li> <li>- does not have the warning statement (PSYLL1) on the label.</li> </ul> <p>(b) When a dose for children is stated, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> <li>- (PSYLL) 'On medical advice' (or words to that effect).</li> </ul>                               |
| 2813                                     | ISPAGHULA HUSK POWDER | A, H     | <p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 March 2020; or</li> <li>- is supplied after 2 March 2021.</li> </ul> <p>(a) When a dose for children is stated, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> <li>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</li> </ul> <p>The requirement specified in paragraph (b) below applies in relation to a medicine that</p> |

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|--|-----------------------------|----------|--|
| Column 1                                 | Column 2                    | Column 3 | Column 4   |
| Item                                     | Ingredient name             | Purpose  | Specific requirements  |
|  |                             |          | contains the ingredient that:<br>- is listed in the Register before 2 March 2020; and<br>- is supplied before 2 March 2021; and<br>- does not have the warning statement (PSYLL1) on the label.<br><br>(b) When a dose for children is stated, the following warning statement is required on the label:<br>- (PSYLL) 'On medical advice' (or words to that effect). |
| 2814                                     | IVA AXILLARIS               | A, H     |  |
| 2815                                     | JAMAICA DOGWOOD BARK DRY    | A, H     |  |
| 2816                                     | JAMAICA DOGWOOD BARK POWDER | A, H     |  |
| 2817                                     | JASMINE 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%.   |
| 2818                                     | JASMINE LACTONE             | E        | Only for use in topical medicines for dermal application.  |
| 2819                                     | JASMINE OIL                 | E        | Permitted for use only in  |

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| Column 1                                 | Column 2              | Column 3 | Column 4  |
| Item                                     | Ingredient name       | Purpose  | Specific requirements   |
|  |                       |          | 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%.                           |
| 2820                                     | JASMINUM GRANDIFLORUM | 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%.       |
| 2821                                     | JASMINUM OFFICINALE   | A, E, H  |   |
| 2822                                     | JASSOLIA              | 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%. |
| 2823                                     | JATEORHIZA PALMATA    | A, H     |   |
| 2824                                     | JATROPHA CURCAS       | H        | Only for use as an active homoeopathic ingredient   |
| 2825                                     | JERUSALEM ARTICHOKE   | E        |   |
| 2826                                     | JOJOBA ESTERS         | E        | Only for use in topical medicines for dermal application and not to be included in medicines intended   |

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| Column 1                                 | Column 2                         | Column 3 | Column 4  |
| Item                                     | Ingredient name                  | Purpose  | Specific requirements   |
|  |                                  |          | for use in the eye.<br>The concentration in the medicine must be no more than 25%.  |
| 2827                                     | JUGLANS CINEREA                  | A, E, H  |   |
| 2828                                     | JUGLANS NIGRA                    | A, E, H  |   |
| 2829                                     | JUGLANS REGIA                    | A, H     |   |
| 2830                                     | JUNCUS EFFUSUS                   | A, H     |   |
| 2831                                     | JUNIPER BERRY OIL                | A, E, H  |   |
| 2832                                     | JUNIPER BERRY OIL<br>TERPENELESS | 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%. |
| 2833                                     | JUNIPERUS CALIFORNICA            | A, H     |   |
| 2834                                     | JUNIPERUS COMMUNIS               | A, E, H  |   |
| 2835                                     | JUNIPERUS MEXICANA               | 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%. |
| 2836                                     | JUNIPERUS OXYCEDRUS              | A, H     |   |
| 2837                                     | JUNIPERUS VIRGINIANA             | A, E, H  |   |
| 2838                                     | JUSTICIA ADHATODA                | A, H     |   |

