

**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			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
2160	FABIANA IMBRICATA	A, H	
2161	FAGOPYRUM ESCULENTUM	A, H	
2162	FAGUS GRANDIFOLIA	A, H	
2163	FAGUS SYLVATICA	A, H	
2164	FALLOPIA MULTIFLORA	A, H	When for oral use, the medicine requires the following warning statement on the medicine label: - (FALLMUL) 'Warning: Fallopia multiflora may harm the liver in some people. Use under the supervision of a healthcare professional.'
2165	FARNESOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2166	FARNESYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than

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			5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
2167	FAST GREEN FCF	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2168	FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2169	FENCHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2170	FENCHYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more 1%.
2171	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>
2172	FENNEL LEAF	E	
2173	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 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</li> </ul>

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			pregnant or likely to become pregnant (or words to that effect).' - (BREASF) 'Do not use while breastfeeding.'
2174	FENNEL SWEET SEED DRY	A, E, H	When used in oral medicines, the following warning statements are required on the label: - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.'
2175	FENUGREEK	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2176	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%.
2177	FERRIC AMMONIUM CITRATE	A, E, H	When for internal use, iron is a mandatory component of ferric ammonium citrate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of

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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>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>
2178	FERRIC CHLORIDE	A, E, H	When for internal use, iron is a mandatory component of ferric

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			<p>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 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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2179	FERRIC CHLORIDE 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> <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</p>

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			<p>medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2180	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</p>



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			indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2181	FERRIC OXIDE	E	
2182	FERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2183	FERRIC PYROPHOSPHATE	A, H	When for internal use, iron is a mandatory component of ferric pyrophosphate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. 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. 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%). 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. Undivided preparations

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>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>
2184	FERROSFERRIC 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>
2185	FERROSFERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2186	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</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>
2187	FERROUS GLUCONATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferrous gluconate.</p> <p>When for internal use, the</p>

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			<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 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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2188	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 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>

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			- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2189	FERROUS IODIDE	H	Only for use as an active homoeopathic ingredient.
2190	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 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>

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			<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>
2191	FERROUS PHOSPHATE 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</p>

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			<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>
2192	FERROUS PICRATE	H	Only for use as an active homoeopathic ingredient.
2193	FERROUS SULFATE	A, E, H	<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</p>



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			<p>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>
2194	FERROUS SULFATE 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>

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			<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>
2195	FERULA ASSA-FOETIDA	A, E, H	
2196	FERULA FOETIDA	A, E, H	
2197	FERULA GALBANIFLUA	A, E, H	
2198	FERULA RUBRICAULIS	A, E, H	
2199	FERULA SUMBUL	A, H	
2200	FERULIC ACID	E	Only for use in topical medicines for dermal application.
2201	FESTUCA ELATIOR	A, H	
2202	FEVERFEW HERB DRY	A, H	
2203	FEVERFEW HERB POWDER	A, H	

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2204	FICUS CARICA	A, E, H	
2205	FICUS PUMILA	A, H	
2206	FIG	E	
2207	FIG DRY	A, H	
2208	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 delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that</li> </ul>

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			<p>effect).</p> <p>When for use in topical medicines for dermal application:</p> <p>i) the concentration of methyl salicylate in the medicine must not be more than 25%;</p> <p>ii) the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</li> </ul> <p>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (IRRIT) 'If irritation develops, discontinue use'.</li> </ul>
2209	FIR BALSAM ABSOLUTE	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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2210	FIR NEEDLE OIL CANADIAN	A, E	
2211	FIR NEEDLE OIL SIBERIAN	A, E	
2212	FIRMIANA SIMPLEX	A, E, H	
2213	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2214	FLEMINGIA MACROPHYLLA	A, H	
2215	FLOUVE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2216	FLUORESCEIN SODIUM	E	
2217	FOENICULUM VULGARE	A, E, H	When used in oral medicines, the following warning statements are required on the label: - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.' 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. When the plant preparation is oil or distillate and the concentration of methyl

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			<p>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> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
2218	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 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>
2219	FOOD ORANGE 6	E	Permitted for use only as a

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			colour in medicines limited to topical and oral routes of administration.
2220	FOOD ORANGE 7	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2221	FOOD RED 13	E	Permitted for use only as a colour for topical use.
2222	FORMALDEHYDE/MELAMINE/TOSYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
2223	FORMIC ACID	H	Only for use as an active homoeopathic ingredient.
2224	FORSYTHIA SUSPENSIA	A, H	
2225	FORTIFIED WINE	E	Ethanol is a mandatory component of fortified wine. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'.
2226	FRACTIONATED COCONUT OIL	E	
2227	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

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			British Pharmacopoeia, as in force or existing from time to time.
2228	FRAGARIA CHILOENSIS	A, E, H	
2229	FRAGARIA VESCA	A, E, H	
2230	FRAGARIA VIRGINIANA	A, E, H	
2231	FRAGARIA X ANANASSA	A, E, H	
2232	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</p>



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			<p>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>
2233	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 recommended';</li> <li>- (LAX2) 'Prolonged use may</li> </ul>

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			<p>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]'.            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]'.            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            - (LAX4) 'This product may have laxative effect'.            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> <p>- (CHILD3) 'Use in children under 12 years is not recommended';            - (LAX1) 'Drink plenty of water [or words to that effect]';            and</p>

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			- (LAX2) 'Prolonged use may cause serious bowel problems'.
2234	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> <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';</li> </ul> <p>and</p> <ul style="list-style-type: none"> <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 on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product</li> </ul>

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			contains [name of the herb(s) or the chemical component(s)]; and - (LAX4) 'This product may have laxative effect'. 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: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
2235	FRAXINUS AMERICANA	A, H	
2236	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A, H	
2237	FRAXINUS EXCELSIOR	A, H	
2238	FRAXINUS ORNUS	A, H	
2239	FRITILLARIA CIRRHOSA	A, H	
2240	FRITILLARIA THUNBERGII	A, H	
2241	FRITILLARIA VERTICILLATA	A, H	
2242	FRUCTOOLIGOSACCHARIDES	A, E	
2243	FRUCTOSE	A, E, H	
2244	FUCUS VESICULOSUS	A, E, H	Iodine is a mandatory component of Fucus vesiculosus. Only for external use when the concentration of available iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.

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			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2245	FUMARIA OFFICINALIS	A, E, H	
2246	FUMARIC ACID	E, H	Only for use as an active homoeopathic or excipient ingredient.
2247	FUMITORY HERB DRY	A, H	
2248	FUMITORY HERB POWDER	A, H	
2249	FURAMINTON	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2250	FURFURAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2251	FURFURYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

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2252	FURFURYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2253	FURFURYL MERCAPTAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2254	FUSEL OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2255	GALBANUM OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2256	GALBANUM PHENOL	E	Permitted for use only in

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			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2257	GALBANUM RESIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2258	GALBANUM RESINOID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2259	GALEGA OFFICINALIS	A, H	
2260	GALEOPSIS SEGETUM	A, H	
2261	GALIUM APARINE	A, H	
2262	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%.
2263	GALIUM PALUSTRE	A, H	
2264	GALIUM VERUM	A, H	

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2265	GALL STONE	H	Only for use as an active homoeopathic ingredient.
2266	GALPHIMIA GLAUCA	A, H	
2267	GAMMA-4-DIMETHYL-3-CYCLOHEXENE-1-PROPANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2268	GAMMA-BUTYROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2269	GAMMA-CYCLODEXTRIN	E	
2270	GAMMA-DECALACTONE	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.  When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
2271	GAMMA-DODECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total



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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2272	GAMMA-HEPTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2273	GAMMA-HEXALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2274	GAMMA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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2275	GAMMA-LINOLEIC ACID	E	Only for use in topical medicines for dermal application.
2276	GAMMA-LINOLENIC ACID	E	
2277	GAMMA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2278	GAMMA-NONALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2279	GAMMA-OCTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2280	GAMMA-TERPINENE	E	Permitted for use only in

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			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2281	GAMMA-TOCOPHEROL	E	
2282	GAMMA-UNDECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2283	GAMMA-VALEROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2284	GANODERMA LUCIDUM	A, E, H	
2285	GARCINIA GUMMI-GUTTA	A	Only for use in oral medicines. Must be obtained from the rind of the fruit only. Must not contain any directions for use for children or pregnant or lactating women.
2286	GARCINIA QUAESITA	A, H	

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2287	GARDEN BEAN	E	
2288	GARDENIA JASMINOIDES	A, E	
2289	GARDENIA TAHITENSIS 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.  The concentration in the medicine must be no more than 0.002%
2290	GARLIC BULB DRY	A, E, H	
2291	GARLIC BULB FRESH	A, H	
2292	GARLIC BULB POWDER	A, E, H	
2293	GARLIC CLOVE POWDER	A, H	
2294	GARLIC OIL	A, E, H	
2295	GASTRODIA ELATA	A, H	
2296	GAULTHERIA PROCUMBENS	A, E, H	Methyl salicylate is a mandatory component of Gaultheria procumbens.  Not to be included in medicines for use in the eye or on damaged skin.  When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.  When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.  When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:

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			<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 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</li> </ul>

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			medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
2297	GELATIN	A, E	
2298	GELIDIUM AMANSII	A, H	Iodine is a mandatory component of Gelidium amansii. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2299	GELLAN GUM	E	
2300	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%.
2301	GELSEMIUM POWDER	A, H	
2302	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%.
2303	GENET ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2304	GENTIAN DRY	A, H	
2305	GENTIAN POWDER	A, H	
2306	GENTIANA LUTEA	A, E, H	
2307	GENTIANA MACROPHYLLA	A, H	
2308	GENTIANA RHODANTHA	A, H	
2309	GENTIANA SCABRA	A, H	
2310	GENTIANELLA AMARELLA	A, H	
2311	GERANIAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2312	GERANIC ACID	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2313	GERANIOL	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a

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			medicine must be no more than 5%.
2314	GERANIUM	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2315	GERANIUM MACULATUM	A, E, H	
2316	GERANIUM OIL	A, E, H	
2317	GERANIUM OIL SAPONIFIED	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2318	GERANIUM OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2319	GERANIUM ROBERTIANUM	A, E, H	
2320	GERANIUM ROSE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.



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2321	GERANIUM SIBIRICUM	A, E, H	
2322	GERANYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2323	GERANYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2324	GERANYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2325	GERANYL CROTONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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			fragrance concentration in a medicine must be no more than 1%.
2326	GERANYL ETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2327	GERANYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2328	GERANYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2329	GERANYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2330	GERANYL NITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2331	GERANYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2332	GERANYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2333	GEUM RIVALE	A, H	
2334	GEUM URBANUM	A, H	
2335	GHATTI GUM	A, E, H	
2336	GIGARTINA MAMILLOSA	A, H	Iodine is a mandatory component of Gigartina mamillosa.

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			<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>
2337	GINGER DRY	A, E, H	
2338	GINGER OIL	A, E, H	
2339	GINGER OLEORESIN	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 the medicine must be no more than 5%.</p>
2340	GINGER POWDER	A, E, H	
2341	GINKGO BILOBA	A, E, H	<p>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.</p>
2342	GLACIAL ACETIC ACID	E, H	<p>The concentration in the medicine must be no more than 1.5%.</p>

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2343	GLECHOMA HEDERACEA	A, H	
2344	GLECHOMA LONGITUBA	A, H	
2345	GLEDITSIA AUSTRALIS	A, H	
2346	GLEDITSIA SINENSIS	A, H	
2347	GLEHNNIA LITTORALIS	A, H	
2348	GLORIOSA SUPERBA	A, H	Colchicine is a mandatory component of <i>Gloriosa superba</i> and must be declared in the application. The concentration of colchicine in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
2349	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2350	GLUCONOLACTONE	E	
2351	GLUCOSAMINE HYDROCHLORIDE	A, E	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2352	GLUCOSAMINE SULFATE	A	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2353	GLUCOSAMINE SULFATE POTASSIUM CHLORIDE	A	Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride. When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from

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			seafood'. When for oral use, the medicine requires the following warning statement on the medicine label: - (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.'
2354	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2355	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: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or

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2356	GLUCOSE GLUTAMATE	E	Only for use in topical medicines for dermal application.
2357	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: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
2358	GLUCOSYLRUTIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
2359	GLUTAMIC ACID	A, E	Only for use in topical medicines for dermal

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2360	GLUTAMIC ACID HYDROCHLORIDE	A, E, H	
2361	GLUTAMINE	A, E, H	
2362	GLUTARAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2363	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.  The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (ADULT) 'Adults only' (or words to that effect).
2364	GLUTEN-FREE WHEAT STARCH	E	
2365	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.  The concentration in the medicine must be no more than 7%.
2366	GLYCEROL	A, E	When used as an active



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			ingredient, it is only for use in topical medicines for dermal application.
2367	GLYCEROL ESTER OF PARTIALLY HYDROGENATED GUM ROSIN	E	<p>Only for use when the dosage form is 'chewing gum'.</p> <p>Must comply with:</p> <p>a) the Glycerol Ester of Partially Hydrogenated 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</p> <p>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.</p>
2368	GLYCERYL BEHENATE	E	<p>Behenic acid is a mandatory component of glyceryl behenate.</p> <p>When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.</p> <p>In medicines for topical use, the concentration of glyceryl behenate must be no more than 5%.</p>
2369	GLYCERYL CAPRYLATE	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 1%.</p>

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2370	GLYCERYL DIISOSTEARATE	E	For use in topical medicines for dermal application.
2371	GLYCERYL DILAURATE	E	Only for use in topical medicines for dermal application.
2372	GLYCERYL DIOLEATE	E	Only for use in topical medicines for dermal application.
2373	GLYCERYL DISTEARATE	E	Only for use in topical medicines for dermal application.
2374	GLYCERYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2375	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. The concentration in the medicine must be no more than 5.5%.
2376	GLYCERYL LAURATE	E	Only for use in topical medicines for dermal application.
2377	GLYCERYL LINOLEATE	E	Only for use in topical medicines for dermal application.

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2378	GLYCERYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2379	GLYCERYL MONOOLEATE	E	
2380	GLYCERYL MONOSTEARATE	E	
2381	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2382	GLYCERYL OLEATE CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4% of the formulation.
2383	GLYCERYL PALMITO- STEARATE	E	
2384	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. The concentration in the medicine must be no more than 0.15%.
2385	GLYCERYL POLYMETHACRYLATE	E	Only for use in topical medicines for dermal application.
2386	GLYCERYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2387	GLYCERYL ROSINATE	E	Only for use when the dosage form is 'chewing gum'.

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

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2392	GLYCERYL TRIACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2393	GLYCERYL TRINITRATE	H	Only for use as an active homoeopathic ingredient.
2394	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%.
2395	GLYCINE	A, E	
2396	GLYCINE MAX	A, E, H	
2397	GLYCOGEN	E	Only for use in topical medicines for dermal application.
2398	GLYCOL DISTEARATE	E	Only for use in topical medicines for dermal application.
2399	GLYCOLIC ACID	E	Only for use in topical medicines for dermal application. 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. When present as an excipient in sunscreens, the concentration in the medicine must be no more than 5%. When used as an excipient

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			ingredient in other medicines the concentration in the medicine must be no more than 20%. If the concentration is more than 5% but no more than 20%, the pH of the medicine must be 3.5 or greater.
2400	GLYCYRRHIZA GLABRA	A, E, H	
2401	GLYCYRRHIZA SPECIES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2402	GLYCYRRHIZA URALENSIS	A, E, H	
2403	GLYCYRRHIZINIC ACID	E	
2404	GNAPHALIUM AFFINE	A, H	
2405	GNAPHALIUM POLYCEPHALUM	A, H	
2406	GNAPHALIUM ULIGINOSUM	A, H	
2407	GOAT	H	Only for use as an active homoeopathic ingredient.
2408	GOAT MILK	E	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
2409	GOLD	E, H	Only for use as an active homoeopathic or excipient ingredient.
2410	GOLD CHLORIDE	H	Only for use as an active homoeopathic ingredient.

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2411	GOLDEN ROD HERB DRY	A, E, H	
2412	GOLDEN SEAL ROOT DRY	A, H	
2413	GOLDEN SEAL ROOT POWDER	A, H	
2414	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 the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
2415	GOMPHRENA GLOBOSA	A, H	
2416	GOOSEBERRY	E	
2417	GOSSYPIUM HERBACEUM	A, E, H	
2418	GRAPE	E	
2419	GRAPE SEED OIL	E	
2420	GRAPE WINE RED	E	Ethanol is a mandatory component of Grape wine red.

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			When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2421	GRAPE WINE SHERRY	E	Ethanol is a mandatory component of Grape wine sherry. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2422	GRAPE WINE WHITE	E	Ethanol is a mandatory component of Grape wine white. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2423	GRAPEFRUIT	E	
2424	GRAPEFRUIT OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.



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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2425	GRAPEFRUIT OIL COLDPRESSED	A, E, H	
2426	GRAPEFRUIT OIL CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2427	GRAPEFRUIT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2428	GRAPEFRUIT OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2429	GRAPHITE	H	Only for use as an active homoeopathic ingredient.
2430	GRATIOLA LINIFOLIA	A, H	
2431	GREATER NETTLE HERB DRY	A, H	

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2432	GREATER NETTLE HERB POWDER	A, H	
2433	GREATER NETTLE ROOT DRY	A, H	
2434	GREATER NETTLE ROOT POWDER	A, H	
2435	GREEN LIPPED MUSSEL	A	
2436	GREEN LIPPED MUSSEL DRIED	A	
2437	GREEN LIPPED MUSSEL OIL	A	
2438	GREEN S	E	Only for use as a colour in topical and oral medicines.
2439	GRIFOLA FRONDOSA	A	When the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label:  -(WARF) 'Do not take while on warfarin therapy without medical advice.'
2440	GRINDELIA CAMPORUM	A, H	
2441	GRINDELIA ROBUSTA	A, H	
2442	GRISALVA	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2443	GROUND IVY HERB DRY	A, H	
2444	GROUND IVY HERB POWDER	A, H	
2445	GUAIAIC WOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2446	GUAIACOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
2447	GUAIACUM OFFICINALE	A, E, H	
2448	GUAIACUM RESIN	A, E, H	
2449	GUAIACUM SANCTUM	A, H	
2450	GUAIENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2451	GUAIYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2452	GUANINE	E	Only for use as an excipient in topical medicines for dermal application.
2453	GUANOSINE	E	Only for use in topical medicines for dermal

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			application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 0.01% in the medicine.
2454	GUAR GALACTOMANNAN	A	When for oral use: (a) the maximum daily dose must provide no more than 25 g of guar galactomannan; (b) the medicine requires the following dosage instructions: - (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) (c) when the dosage form is a powder preparation, the medicine requires the following dosage instructions: - (DNTPOW) 'Do not take powder alone. Mix with food or fluid.' (or words to that effect).
2455	GUAR GUM	A, E, H	
2456	GUAR HYDROXYPROPYLTRIMONIUM 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. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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			1%.
2460	GYMNADENIA NIGRA	A	
2461	GYMNEMA SYLVESTRE	A, H	
2462	GYMNOCLADUS DIOICA	A, H	
2463	GYNOSTEMMA 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 MERCURY	H	Only for use as an active homoeopathic ingredient.
2466	HALIBUT-LIVER OIL	A, E	<p>Colecalciferol and Vitamin A are mandatory components of Halibut-liver oil.</p> <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> <p>- (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not</p>

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			take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.
			- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.
			- (VITA3) ‘The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’
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 HEPTAPHYLLUS	A, H	
2472	HANDROANTHUS IMPETIGINOSUS	A, E, H	
2473	HARD FAT	E	
2474	HARD PARAFFIN	E	
2475	HARICOT BEAN	E	
2476	HARPAGOPHYTUM PROCUMBENS	A, E, H	
2477	HARUNGANA MADAGASCARIENSIS	A, H	
2478	HAZEL NUT	E	
2479	HAZEL NUT OIL	E	
2480	HEAVY KAOLIN	E	

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2481	HEAVY MAGNESIUM OXIDE	A, E, H	
2482	HECTORITE	E	Only for use in topical medicines for dermal application.
2483	HEDEOMA PULEGIOIDES	A	
2484	HEDERA HELIX	A, H	Emetine is a mandatory component of Hedera helix. 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. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2488	HELIANTHEMUM NUMMULARIUM	A, H	
2489	HELIANTHUS ANNUUS	A, E, H	
2490	HELIANTHUS TUBEROSUS	A, H	
2491	HELICHRYSUM 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. If used in a fragrance the total

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			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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2500	HEPTANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2501	HEPTANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.



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			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
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 medicine must be no more than 5%.</p>
2505	HEPTYL UNDECYLENATE	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 of the medicine must be no more than</p>

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			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. 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. 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 flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2512	HEXAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			5%. 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%. 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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2515	HEXANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2516	HEXASODIUM FYTATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines

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			intended for use in the eye or on damaged skin. 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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2518	HEXYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2519	HEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2520	HEXYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			medicine must be no more than 5%. 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. 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. 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. 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. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

<b>Permissible ingredients and requirements</b>			
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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
2525	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2526	HEXYL NICOTINATE	E	
2527	HEXYL PROPIONATE	E	Only for use in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation.  The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
2528	HEXYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2529	HEXYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2530	HEXYLDECANOL	E	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.  The concentration of the medicine must be no more than 3%.

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
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. The medicine of must not contain more than 2.5 mg of hexylresorcinol per lozenge. The maximum recommended daily dose of the medicine must not provide more than 30mg of hexylresorcinol. The medicine label must specify that the medicine is only to be used for 7 days (or less). The following warning statement must be included on the medicine label: - (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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2536	HIBISCUS SABDARIFFA	A, E, H	
2537	HIERACIUM PILOSELLA	A, H	
2538	HIGH AMYLOSE MAIZE STARCH	A, E, H	

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
2539	HIGH CHROMIUM YEAST	A, E	<p>Chromium is a mandatory component of high chromium yeast.</p> <p>The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic chromium sources.</p> <p>High chromium yeast is considered to be an organic form of chromium.</p>
2540	HIGH FRUCTOSE MAIZE SYRUP	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>
2541	HIGH MOLYBDENUM YEAST	A, E	<p>Molybdenum is a mandatory component of high molybdenum yeast.</p> <p>The maximum daily dose of molybdenum from high molybdenum yeast must be no more than 62.5 micrograms.</p>
2542	HIGH SELENIUM YEAST	A	<p>When for oral or sublingual use, selenium is a mandatory component of high selenium yeast.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine contains selenium which is</p>



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			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 Hirschfeldia incana when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
2546	HISTAMINE 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 flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2550	HO WOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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			5%. 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. For use as an excipient only in topical medicines for dermal application. Not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 15%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2556	HONEY	A, E	When the route of administration is oral, the medicine requires the following warning statement on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).

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			<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 the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
2557	HONEY BEE	H	Only for use as an active homoeopathic ingredient.
2558	HONEY EXTRACT	E	<p>Not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</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</p>

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			on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.
2559	HONEY POWDER	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
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.  If used in a flavour the total flavour concentration in a medicine must be no more than

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			5%.
2566	HORSE RADISH	E, H	Volatile oil components (of <i>Armoracia rusticana</i> ) is a mandatory component of Horse radish.  The maximum recommended 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 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	HYDRANGEA ARBORESCENS	A, H	
2574	HYDRANGEA 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	
2579	HYDROFLUORIC ACID	H	Only for use as an active

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			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	<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 7%.</p>

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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. The concentration in the medicine must be no more than 3%.
2586	HYDROGENATED COCONUT OIL	E	
2587	HYDROGENATED COTTONSEED OIL	E	
2588	HYDROGENATED DIMER 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. 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%.
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. 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

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			included in medicines intended for use in the eye. 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. 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. The concentration in the medicine must be no more than 1.2%.
2595	HYDROGENATED PALM OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. Polycyclic aromatic hydrocarbons must be kept below the level of detection.
2596	HYDROGENATED POLYDECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.



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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 hydrogenated polydextrose.</li> </ul>
2598	HYDROGENATED POLYISOBUTENE	E	Only for use in topical medicines for dermal application.
2599	HYDROGENATED SOYA OIL	E	
2600	HYDROGENATED TALLOW GLYCERIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p>
2601	HYDROGENATED VEGETABLE OIL	E	
2602	HYDROLIAC	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total</p>

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			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.  The concentration in the medicine must be no more than 0.01%
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.  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.  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

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			medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
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. 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. 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. 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

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			wheat protein.
2619	HYDROLYSED WHEAT PROTEIN/PVP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.  The concentration in the medicine must be no more than 1.2%.
2620	HYDROLYSED YEAST 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 or on damaged skin.  The concentration in the medicine must be no more than 0.3%.
2621	HYDROQUINONE DIMETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2622	HYDROUS WOOL FAT	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.

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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. 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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2629	HYDROXYCITRONELLAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more 1%.
2630	HYDROXYCITRONELLAL- METHYLANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2631	HYDROXYCITRONELLOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2632	HYDROXYETHYL CETEARAMIDOPROPYLDIMONI UM CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 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. The concentration must be no more than 1%.
2634	HYDROXYLATED LANOLIN	E	
2635	HYDROXYLATED MILK	E	Only for use in topical

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	GLYCERIDES		medicines for dermal application and not to be included in topical medicines intended for use in the eye. 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	HYDROXPALMITOYL 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. The concentration must be no more than 0.1%.
2640	HYDROXYPROLINE	A, E	
2641	HYDROXYPROPYL DISTARCH PHOSPHATE	E	Only permitted for: - use in topical medicines for dermal application; and - medicines for internal use. When for use in topical medicines for dermal application: - not to be included medicines intended for use in the eye or damaged skin; and - the concentration of hydroxypropyl distarch phosphate in the medicine must be no more than 4%. When for internal use, the maximum recommended daily dose must not contain more than 240mg of hydroxypropyl distarch phosphate.

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2642	HYDROXYPROPYL STARCH	E	
2643	HYDROXYPROPYLBETADEX	E	Only for use in topical medicines for dermal application.
2644	HYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 9%.
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 hyoscyne are mandatory components of Hyoscamus leaf dry. 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%. The concentration of hyoscyne 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 hyoscyne are mandatory components of Hyoscamus leaf powder.



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			<p>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%.</p> <p>The concentration of hyoscyine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.</p>
2651	HYOSCYAMUS NIGER	A, H	<p>Alkaloids calculated as hyoscyamine and hyoscyine are mandatory components of <i>Hyoscyamus niger</i>.</p> <p>The concentration of hyoscyamine in the medicine must be no more than 3 micrograms/kg or 3 micrograms/L or 0.3%.</p> <p>The concentration of hyoscyine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.</p>
2652	HYPERICUM ASCYRON	A, H	
2653	HYPERICUM JAPONICUM	A, H	
2654	HYPERICUM PERFORATUM	A, E, H	<p>When used for oral ingestion, the medicine requires the following warning statement on the medicine label:</p> <p>- (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'</p>
2655	HYPROLOSE	E	
2656	HYPROMELLOSE	E	
2657	HYPROMELLOSE PHTHALATE	E	

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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 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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			<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 intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</li> </ul> <p>e) When the maximum recommended daily dose of the</p>

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			<p>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	ILLICIIUM 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: <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect).</li> </ul> </li> </ul>
2668	IMIDUREA	E	Only for use in topical medicines for dermal application.

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2669	IMMORTELLE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2670	IMMORTELLE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2671	IMPATIENS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
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

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2677	INDIGOFERA TINCTORIA	A, H	
2678	INDISAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2679	INDOLE	E, H	Only for use as an active homoeopathic or excipient ingredient. 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. 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. The concentration in the

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			medicine must be no more than 1.2%.
2688	INVERT SUGAR	E	<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 100 mg 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 the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
2689	INVERT SYRUP	E	<p>Glucose is a mandatory component of Invert syrup when the route of administration 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 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p>

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			<p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
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 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</p>



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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
2693	IOPAMIDOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2694	IPECACUANHA DRY	A, H	Emetine is a mandatory component of Ipecacuanha Dry. 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. 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. 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. The concentration of emetine in the medicine must be no

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			more than 0.2%.
2698	IPOMOEA BATATAS	A, H	
2699	IPOMOEA JALAPA	A, H	
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 present as an excipient at a</p>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>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 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>

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			<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 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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			<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>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 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 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>
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</p>

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			<p>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 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</p>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<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>
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 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>



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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 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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			treatment of iron deficiency conditions' (or words to that effect).
2716	IRONE	E	
2717	IRVINGIA GABONENSIS SEED TRIGLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. 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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2720	ISOAMYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2721	ISOAMYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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			5%. If used in a fragrance the total fragrance concentration in a 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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2723	ISOAMYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2724	ISOAMYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2725	ISOAMYL CAPRYLATE	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
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> <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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2729	ISOAMYL HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2730	ISOAMYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2731	ISOAMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
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.

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			The concentration must be no more than 12%.
2733	ISOAMYL METHOXYCINNAMATE	A	<p>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.</p> <p>The concentration in the medicine must not be more than 10%.</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>
2734	ISOAMYL PHENYLACETATE	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>
2735	ISOAMYL PHENYLETHYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than</p>

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			1%.
2736	ISOAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2737	ISOAMYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2738	ISOBERGAMIATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2739	ISOBORNEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2740	ISOBORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2741	ISOBORNYL CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2744	ISOBUTYL ALCOHOL	E	The residual solvent limit for



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			Isobutyl alcohol is 50mg per recommended daily dose. 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 flavour. 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. 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. 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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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2749	ISOBUTYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2750	ISOBUTYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2751	ISOBUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.  Medicines containing hydroxybenzoates require the following warning statement on the medicine label:  - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
2752	ISOBUTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than

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			5%. 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. 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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2755	ISOBUTYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2756	ISOBUTYL QUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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2757	ISOBUTYL SALICYLATE	E	Only for use in topical medicines for dermal application.
2758	ISOBUTYLENE/ISOPRENE COPOLYMER	E	Only for oral use when the dosage form is chewing gum. The concentration must be consistent with best practice for the production of gum delivery systems.
2759	ISOBUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2760	ISOBUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
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.

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
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. The concentration must be no more than 10%.
2765	ISOCYCLOCITRAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
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 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. The concentration must be no more than 2%.

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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. 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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2773	ISOEUGENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2774	ISOEUGENYL BENZYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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			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. The total flavour proprietary excipient formulation in a medicine must not be more than 5%. The total fragrance proprietary excipient formulation in a medicine must not be more than 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: - (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

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			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2780	ISOMETHYLIONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2781	ISONONYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2782	ISONONYL ISONONANOATE	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. The concentration must be no more than 15%.
2783	ISOPENTANE	E	For dental use only. The concentration must be no more than 2%.
2784	ISOPENTANOIC ACID	E	Permitted for use only in combination with other



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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2785	ISOPHORONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2786	ISOPHYTOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2787	ISOPROPYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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2788	ISOPROPYL 4-HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application. Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved name of hydroxybenzoate used]’ (or words to this effect) if product contains one hydroxybenzoate source.
2789	ISOPROPYL ACETATE	E	Only for use in topical medicines for dermal application.
2790	ISOPROPYL ALCOHOL	E	
2791	ISOPROPYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2792	ISOPROPYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2793	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal

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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. 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. The concentration must be no more than 10%.
2799	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2800	ISOPROPYL TITANIUM TRIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 0.2%.
2801	ISOPROPYL-3-METHYL-BUTANE THIOATE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. 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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2803	ISORALDEINE 70	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2804	ISOSTEARIC ACID	E	Only for use in topical 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. The concentration must be no more than 0.3%.
2806	ISOSTEARYL ALCOHOL	E	Only for use in topical medicines for dermal

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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. 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. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2810	ISOVALERALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2811	ISOVALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
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 effect).</li> </ul> <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>

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			<p>- is listed in the Register on or after 2 March 2020; or</p> <p>- is supplied after 2 March 2021.</p> <p>(a) When a dose for children is stated, the following warning statement is required on the label:</p> <p>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</p> <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <p>- is listed in the Register before 2 March 2020; and</p> <p>- is supplied before 2 March 2021; and</p> <p>- does not have the warning statement (PSYLL1) on the label.</p> <p>(b) When a dose for children is stated, the following warning statement is required on the label:</p> <p>- (PSYLL) 'On medical advice' (or words to that effect).</p>
2814	IVA AXILLARIS	A, H	
2815	JAMAICA DOGWOOD BARK DRY	A, H	
2816	JAMAICA DOGWOOD BARK POWDER	A, H	
2817	JASMINE 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</p>

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			5%. 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 combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2820	JASMINUM GRANDIFLORUM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2821	JASMINUM OFFICINALE	A, E, H	
2822	JASSOLIA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2823	JATEORHIZA PALMATA	A, H	
2824	JATROPHA CURCAS	H	Only for use as an active homoeopathic ingredient



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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 for use in the eye. 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 TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2833	JUNIPERUS CALIFORNICA	A, H	
2834	JUNIPERUS COMMUNIS	A, E, H	
2835	JUNIPERUS DEPPEANA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2836	JUNIPERUS OXYCEDRUS	A, H	
2837	JUNIPERUS VIRGINIANA	A, E, H	
2838	JUSTICIA ADHATODA	A, H	