

## 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
2170	FABIANA IMBRICATA	A, H	
2171	FAGOPYRUM ESCULENTUM	A, H	
2172	FAGUS GRANDIFOLIA	A, H	
2173	FAGUS SYLVATICA	A, H	
2174	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%.
2175	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 5%.  When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
2176	FAST GREEN FCF	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.

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2177	FENCHONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2178	FENCHYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2179	FENCHYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2180	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>

2181	FENNEL LEAF	E	
2182	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> <p>- (CHILD) 'Keep out of reach of children (or words to that effect).'</p> <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> <p>- (CHILD3) 'Use in children under 12 years is not recommended.'</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect).'</p> <p>- (BREASF) 'Do not use while breastfeeding.'</p>
2183	FENNEL SWEET SEED DRY	A, E, H	<p>When used in oral medicines, the following warning statements are required on the label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended'</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'</p> <p>- (BREASF) 'Do not use while breastfeeding.'</p>
2184	FENUGREEK	E	Permitted for use only in combination with other permitted

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			<p>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>
2185	FENUGREEK OIL	E	<p>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%.</p>
2186	FERRIC AMMONIUM CITRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferric ammonium citrate.</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</p>

			<p>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>
2187	FERRIC CHLORIDE	A, E, H	<p>When for internal use, iron is a mandatory component of ferric chloride.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no 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</p>

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			<p>child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2188	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</p>

			<p>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>
2189	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</p>

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			child resistant closure. 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: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2190	FERRIC OXIDE	E	
2191	FERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2192	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.



			<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: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2193	FERROSOFERRIC OXIDE	E	<p>When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.</p>
2194	FERROSOFERRIC PHOSPHATE	H	<p>Only for use as an active homoeopathic ingredient.</p>
2195	FERROUS FUMARATE	A, H	<p>When for internal use, iron is a mandatory component of ferrous fumarate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack</p>

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			<p>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:          - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2196	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 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</p>

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			<p>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:        - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2197	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</p>

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			<p>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: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2198	FERROUS IODIDE	H	Only for use as an active homoeopathic ingredient.
2199	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</p>

			<p>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:        - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2200	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</p>

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			<p>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:          - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2201	FERROUS PICRATE	H	Only for use as an active homoeopathic ingredient.
2202	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</p>

			<p>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:        - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2203	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</p>

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			<p>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: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2204	FERULA ASSA-FOETIDA	A, E, H	
2205	FERULA FOETIDA	A, E, H	
2206	FERULA GALBANIFLUA	A, E, H	
2207	FERULA RUBRICAULIS	A, E, H	
2208	FERULA SUMBUL	A, H	
2209	FERULIC ACID	E	Only for use in topical medicines for dermal application.



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2210	FESTUCA ELATIOR	A, H	
2211	FEVERFEW HERB DRY	A, H	
2212	FEVERFEW HERB POWDER	A, H	
2213	FICUS CARICA	A, E, H	
2214	FICUS PUMILA	A, H	
2215	FIG	E	
2216	FIG DRY	A, H	
2217	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 effect).</li> </ul>

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			<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>
2218	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>
2219	FIR NEEDLE OIL CANADIAN	A, E	
2220	FIR NEEDLE OIL SIBERIAN	A, E	
2221	FIRMIANA SIMPLEX	A, E, H	
2222	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2223	FLEMINGIA MACROPHYLLA	A, H	
2224	FLOUVE OIL	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>
2225	FLUORESCEIN SODIUM	E	
2226	FOENICULUM VULGARE	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> <p>When the plant preparation is oil or distillate, methyl chavicol is a mandatory component and the maximum daily dose must provide no more than 150 mg of the plant preparation.</p> <p>When the plant preparation is oil or distillate and the concentration of methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL, a restricted flow insert must be fitted on the container, and the following warning statement is required on the label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect).</li> </ul>
2227	FOLIC ACID	A	When for internal use, the maximum recommended daily

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				dose must not provide more than 500 micrograms of folic acid. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.
2228	FOOD ORANGE 6	E		Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2229	FOOD ORANGE 7	E		Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2230	FOOD RED 13	E		Permitted for use only as a colour for topical use.
2231	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%.
2232	FORMIC ACID	E, H		Formic acid must only be included in medicines: (a) as an active homoeopathic ingredient; or (b) when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing formic acid must not be more than 5% of the total medicine. The maximum recommended daily dose of the medicine must not provide more than 150 mg of

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			formic acid. The total concentration of formic acid in the medicine must not be more than 0.5%.
2233	FORSYTHIA SUSPensa	A, H	
2234	FORTIFIED WINE	E	Ethanol is a mandatory component of fortified wine.
2235	FRACTIONATED COCONUT OIL	E	
2236	FRACTIONATED PALM KERNEL OIL	A, E	When used as an active ingredient, can only be supplied as an un compounded medicine substance packed for retail sale, and must comply with an un compounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2237	FRAGARIA CHILOENSIS	A, E, H	
2238	FRAGARIA VESCA	A, E, H	
2239	FRAGARIA VIRGINIANA	A, E, H	
2240	FRAGARIA X ANANASSA	A, E, H	
2241	FRANGULA BARK DRY	A, H	Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark dry. 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: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are

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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:

- (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:

- (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:

- (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'.

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2242

FRANGULA BARK POWDER

A, H

Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark powder.

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:

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- (CHILD3) 'Use in children under 12 years is not recommended';  
 - (LAX2) 'Prolonged use may cause serious bowel problems';  
 and  
 - (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:  
 - (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:  
 - (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:  
 - (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'.

2243	FRANGULA PURSHIANA	A, H	When for oral use,
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hydroxyanthracene derivatives calculated as cascarioside A is a mandatory component of *Frangula purshiana*.

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:

- (CHILD3) 'Use in children under 12 years is not recommended';

- (LAX2) 'Prolonged use may cause serious bowel problems';

and

- (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:

- (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:

- (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

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			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'.
2244	FRAXINUS AMERICANA	A, H	
2245	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A, H	
2246	FRAXINUS EXCELSIOR	A, H	
2247	FRAXINUS ORNUS	A, H	
2248	FRITILLARIA CIRRHOSA	A, H	
2249	FRITILLARIA THUNBERGII	A, H	
2250	FRITILLARIA VERTICILLATA	A, H	
2251	FRUCTOOLIGOSACCHARIDES	A, E	
2252	FRUCTOSE	A, E, H	
2253	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.  Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2254	FULLY HYDROGENATED RAPESEED OIL	E	Fully hydrogenated rapeseed oil must only be used in topical medicines for dermal application.  The total concentration of fully hydrogenated rapeseed oil in the medicine must not be more than 5%.
2255	FUMARIA OFFICINALIS	A, E, H	
2256	FUMARIC ACID	E, H	Only for use as an active

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			homoeopathic or excipient ingredient.
2257	FUMITORY HERB DRY	A, H	
2258	FUMITORY HERB POWDER	A, H	
2259	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%.
2260	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%.
2261	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 5%.
2262	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%.
2263	FURFURYL MERCAPTAN	E	Permitted for use only in combination with other permitted

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			<p>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>
2264	FUSEL OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2265	GALACTOOLIGOSACCHARIDES	A	<p>Only to be used in a medicine where FrieslandCampina Ingredients B V (Client ID 79530), 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 1 May 2025.</p> <p>Lactose and glucose are mandatory components of galactooligosaccharides.</p> <p>The route of administration for medicines that contain galactooligosaccharides must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(a) 8 g of galactooligosaccharides to individuals aged 0 to 3 years (inclusive); and</p> <p>(b) 16.2 g of galactooligosaccharides to individuals aged 4 years and older.</p> <p>The following warning statement (or words to the same effect) is</p>

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			required on the medicine label: (GOS) 'Not to be taken on the same day with other products containing galactooligosaccharides.'
2266	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%.
2267	GALBANUM PHENOL	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	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%.
2269	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

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			fragrance concentration in a medicine must be no more 1%.
2270	GALEGA OFFICINALIS	A, H	
2271	GALEOPSIS SEGETUM	A, H	
2272	GALIUM APARINE	A, H	
2273	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%.
2274	GALIUM PALUSTRE	A, H	
2275	GALIUM VERUM	A, H	
2276	GALL STONE	H	Only for use as an active homoeopathic ingredient.
2277	GALPHIMIA GLAUCA	A, H	
2278	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%.
2279	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%.
2280	GAMMA-CYCLODEXTRIN	E	
2281	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

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			<p>proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
2282	GAMMA-DODECALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2283	GAMMA-HEPTALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2284	GAMMA-HEXALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2285	GAMMA-IONONE	E	<p>Permitted for use only in combination with other permitted</p>

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			<p>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>
2286	GAMMA-LINOLEIC ACID	E	Only for use in topical medicines for dermal application.
2287	GAMMA-LINOLENIC ACID	E	
2288	GAMMA-N-METHYL IONONE	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>
2289	GAMMA-NONALACTONE	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>
2290	GAMMA-OCTALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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			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%.
2291	GAMMA-TERPINENE	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%.
2292	GAMMA-TOCOPHEROL	E	
2293	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%.
2294	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%.
2295	GANODERMA LUCIDUM	A, E, H	
2296	GARCINIA GUMMI-GUTTA	A	Only for use in oral medicines. Must be obtained from the rind of



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			the fruit only. Must not contain any directions for use for children or pregnant or lactating women.
2297	GARCINIA QUAESITA	A, H	
2298	GARDEN BEAN	E	
2299	GARDENIA JASMINOIDES	A, E	
2300	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%
2301	GARLIC BULB DRY	A, E, H	
2302	GARLIC BULB FRESH	A, H	
2303	GARLIC BULB POWDER	A, E, H	
2304	GARLIC CLOVE POWDER	A, H	
2305	GARLIC OIL	A, E, H	
2306	GASTRODIA ELATA	A, H	
2307	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:

- the delivery device is engaged into the container in such a way that prevents it from being readily removed;

- direct suction through the delivery device results in delivery of no more than one dosage unit; and

- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).

When for use in topical medicines for dermal application

i) the concentration of methyl salicylate in the medicine must not be more than 25%;

ii) the following warning statements are required on the medicine label:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);

- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';

- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);

iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:

- (IRRIT) 'If irritation develops, discontinue use'.

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2308	GELATIN	A, E	
2309	GELIDIUM AMANSII	A, H	<p>Iodine is a mandatory component of <i>Gelidium amansii</i>.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
2310	GELLAN GUM	E	
2311	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%.
2312	GELSEMIUM POWDER	A, H	
2313	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%.
2314	GENET ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2315	GENTIAN DRY	A, H	
2316	GENTIAN POWDER	A, H	
2317	GENTIANA LUTEA	A, E, H	

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2318	GENTIANA MACROPHYLLA	A, H	
2319	GENTIANA RHODANTHA	A, H	
2320	GENTIANA SCABRA	A, H	
2321	GENTIANELLA AMARELLA	A, H	
2322	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%.
2323	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%.
2324	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 medicine must be no more than 5%.
2325	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%.
2326	GERANIUM MACULATUM	A, E, H	
2327	GERANIUM OIL	A, E, H	

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2328	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%.
2329	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%.
2330	GERANIUM ROBERTIANUM	A, E, H	
2331	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%.
2332	GERANIUM SIBIRICUM	A, E, H	
2333	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%.
2334	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

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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%.
2335	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%.
2336	GERANYL CROTONATE	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%.
2337	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%.
2338	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

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			fragrance concentration in a medicine must be no more 1%.
2339	GERANYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2340	GERANYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total 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>
2341	GERANYL NITRILE	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>
2342	GERANYL PROPIONATE	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</p>

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			fragrance concentration in a medicine must be no more 1%.
2343	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%.
2344	GEUM RIVALE	A, H	
2345	GEUM URBANUM	A, H	
2346	GHATTI GUM	A, E, H	
2347	GIGARTINA MAMILLOSA	A, H	Iodine is a mandatory component of Gigartina mamilliosa. 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.
2348	GINGER DRY	A, E, H	
2349	GINGER OIL	A, E, H	
2350	GINGER OLEORESIN	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%.
2351	GINGER POWDER	A, E, H	
2352	GINKGO BILOBA	A, E, H	The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered



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			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.
2353	GLACIAL ACETIC ACID	E, H	The concentration in the medicine must be no more than 1.5%.
2354	GLECHOMA HEDERACEA	A, H	
2355	GLECHOMA LONGITUBA	A, H	
2356	GLEDITSIA AUSTRALIS	A, H	
2357	GLEDITSIA SINENSIS	A, H	
2358	GLEHNNIA LITTORALIS	A, H	
2359	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%.
2360	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2361	GLUCONOLACTONE	E	
2362	GLUCOSAMINE HYDROCHLORIDE	A, E	
2363	GLUCOSAMINE SULFATE	A	
2364	GLUCOSAMINE SULFATE POTASSIUM CHLORIDE	A	Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride. When for oral use, the medicine requires the following warning statement on the medicine label: - (POTAS1) '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.'

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2365	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	
2366	GLUCOSE	A, E, H	
2367	GLUCOSE GLUTAMATE	E	Only for use in topical medicines for dermal application.
2368	GLUCOSE MONOHYDRATE	A, E, H	
2369	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%.
2370	GLUTAMIC ACID	A, E	Only for use in topical medicines for dermal application.
2371	GLUTAMIC ACID HYDROCHLORIDE	A, E, H	
2372	GLUTAMINE	A, E, H	
2373	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%.
2374	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)

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			- (ADULT) 'Adults only' (or words to that effect).
2375	GLUTEN-FREE WHEAT STARCH	E	
2376	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%.
2377	GLYCEROL	A, E	When used as an active ingredient, it is only for use in topical medicines for dermal application.
2378	GLYCEROL ESTER OF PARTIALLY HYDROGENATED GUM ROSIN	E	Only for use when the dosage form is 'chewing gum'. Must comply with: 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 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.
2379	GLYCEROL ESTER OF PARTIALLY HYDROGENATED WOOD ROSIN	E	Glycerol ester of partially hydrogenated wood rosin must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application.
2380	GLYCERYL BEHENATE	E	Behenic acid is a mandatory

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			<p>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>
2381	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>
2382	GLYCERYL DIISOSTEARATE	E	<p>For use in topical medicines for dermal application.</p>
2383	GLYCERYL DILAURATE	E	<p>Only for use in topical medicines for dermal application.</p>
2384	GLYCERYL DIOLEATE	E	<p>Only for use in topical medicines for dermal application.</p>
2385	GLYCERYL DISTEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
2386	GLYCERYL GLUCOSIDE	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 5%.</p>
2387	GLYCERYL ISOSTEARATE	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 5.5%.</p>

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2388	GLYCERYL LAURATE	E	Only for use in topical medicines for dermal application.
2389	GLYCERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2390	GLYCERYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2391	GLYCERYL MONO AND DICAPRYLOCAPRATE	E	Only permitted for use in medicines limited to oral routes of administration, or when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The maximum recommended oral daily dose of the medicine must not provide more than 8 mg of glyceryl mono and dicaprylocaprate. The total concentration of fragrance proprietary excipient formulations containing glyceryl mono and dicaprylocaprate must not be more than 1% of the total medicine.
2392	GLYCERYL MONOOLEATE	E	
2393	GLYCERYL MONOSTEARATE	E	
2394	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2395	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.
2396	GLYCERYL PALMITO-STEARATE	E	

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2397	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%.
2398	GLYCERYL POLYMETHACRYLATE	E	Only for use in topical medicines for dermal application.
2399	GLYCERYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2400	GLYCERYL ROSINATE	E	Only for use when the dosage form is 'chewing gum'. Must comply with: 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 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.
2401	GLYCERYL SORBITAN OLEOSTEARATE	E	Only for use in topical medicines for dermal application.
2402	GLYCERYL STARCH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 4%. The residual levels of epichlorohydrin are to be kept below the level of detection.
2403	GLYCERYL STEARATE CITRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine

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			must be no more than 5%.
2404	GLYCERYL TRIACETYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 6%.
2405	GLYCERYL TRIACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2406	GLYCERYL TRINITRATE	H	Only for use as an active homoeopathic ingredient. The total concentration of glyceryl trinitrate in the medicine must not be more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
2407	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%.
2408	GLYCINE	A, E	
2409	GLYCINE MAX	A, E, H	
2410	GLYCOGEN	E	Only for use in topical medicines for dermal application.
2411	GLYCOL DISTEARATE	E	Only for use in topical medicines for dermal application.
2412	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

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			purpose. When present as an excipient in sunscreens, the concentration in the medicine must be no more than 5%. When used as an excipient 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.
2413	GLYCYRRHIZA GLABRA	A, E, H	
2414	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%.
2415	GLYCYRRHIZA URALENSIS	A, E, H	
2416	GLYCYRRHIZINIC ACID	E	
2417	GNAPHALIUM AFFINE	A, H	
2418	GNAPHALIUM POLYCEPHALUM	A, H	
2419	GNAPHALIUM ULIGINOSUM	A, H	
2420	GOAT	H	Only for use as an active homoeopathic ingredient.
2421	GOAT MILK	E	
2422	GOLD	E, H	Only for use as an active homoeopathic or excipient ingredient.
2423	GOLD CHLORIDE	H	Only for use as an active homoeopathic ingredient.
2424	GOLDEN ROD HERB DRY	A, E, H	
2425	GOLDEN SEAL ROOT DRY	A, H	
2426	GOLDEN SEAL ROOT POWDER	A, H	



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2427	GOLDEN SYRUP	E	When the route of administration of the medicine is oral or sublingual, sucrose is a mandatory component of golden syrup.
2428	GOMPHRENA GLOBOSA	A, H	
2429	GOSSYPIUM HERBACEUM	A, E, H	
2430	GRAPE	E	
2431	GRAPE SEED OIL	E	
2432	GRAPE WINE RED	E	Ethanol is a mandatory component of grape wine red.
2433	GRAPE WINE SHERRY	E	Ethanol is a mandatory component of grape wine sherry.
2434	GRAPE WINE WHITE	E	Ethanol is a mandatory component of grape wine white.
2435	GRAPEFRUIT	E	
2436	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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2437	GRAPEFRUIT OIL COLDPRESSED	A, E, H	
2438	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%.
2439	GRAPEFRUIT OIL TERPENELESS	E	Permitted for use only in

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			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%.
2440	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%.
2441	GRAPHITE	H	Only for use as an active homoeopathic ingredient.
2442	GRATIOLA LINIFOLIA	A, H	
2443	GREATER NETTLE HERB DRY	A, H	
2444	GREATER NETTLE HERB POWDER	A, H	
2445	GREATER NETTLE ROOT DRY	A, H	
2446	GREATER NETTLE ROOT POWDER	A, H	
2447	GREEN LIPPED MUSSEL	A	The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
2448	GREEN LIPPED MUSSEL DRIED	A	The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
2449	GREEN LIPPED MUSSEL OIL	A	The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc'

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				or 'Contains mollusc products'.
2450	GREEN S	E		Only for use as a colour in topical and oral medicines.
2451	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.'
2452	GRINDELIA CAMPORUM	A, H		
2453	GRINDELIA ROBUSTA	A, H		
2454	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%.
2455	GROUND IVY HERB DRY	A, H		
2456	GROUND IVY HERB POWDER	A, H		
2457	GUAIAC 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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2458	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

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			medicine must be no more than 5%.
2459	GUAIACUM OFFICINALE	A, E, H	
2460	GUAIACUM RESIN	A, E, H	
2461	GUAIACUM SANCTUM	A, H	
2462	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%.
2463	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%.
2464	GUANINE	E	Only for use as an excipient in topical medicines for dermal application.
2465	GUANOSINE	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 0.01% in the medicine.
2466	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.'

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			(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).
2467	GUAR GUM	A, E, H	
2468	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	E	Only for use as an excipient in topical medicines for dermal application.
2469	GUAREA RUSBYI	A, H	
2470	GUAVA	E	
2471	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 1%.
2472	GYMNADENIA NIGRA	A	
2473	GYMNEMA SYLVESTRE	A, H	
2474	GYMNOCLADUS DIOICA	A, H	
2475	GYNOSTEMMA PENTAPHYLLUM	A	The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).
2476	HAHNEMANN'S SOLUBLE MERCURY	H	Only for use as an active homoeopathic ingredient.
2477	HALIBUT-LIVER OIL	A, E	Colecalciferol and Vitamin A are mandatory components of Halibut-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. When for use in topical medicines,

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the concentration of Vitamin A in the medicine must be no more than 1%.

When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.

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:

- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.

- (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.’

2478	HAMAMELIS LEAF DRY	A, H
2479	HAMAMELIS LEAF POWDER	A, H
2480	HAMAMELIS VIRGINIANA	A, E, H
2481	HAMAMELIS WATER	A, E, H
2482	HANDROANTHUS HEPTAPHYLLUS	A, H

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2483	HANDROANTHUS IMPETIGINOSUS	A, E, H	
2484	HARD FAT	E	
2485	HARD PARAFFIN	E	
2486	HARICOT BEAN	E	
2487	HARPAGOPHYTUM PROCUMBENS	A, E, H	
2488	HARUNGANA MADAGASCARIENSIS	A, H	
2489	HAZEL NUT	E	
2490	HAZEL NUT OIL	E	
2491	HEAVY KAOLIN	E	
2492	HEAVY MAGNESIUM OXIDE	A, E, H	<p>Magnesium is a mandatory component of heavy magnesium oxide.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be</p>

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			directed for use in infants younger than 12 months of age.
2493	HECTORITE	E	Only for use in topical medicines for dermal application.
2494	HEDEOMA PULEGIOIDES	A	
2495	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%.
2496	HEDTA	E	Only for use as an excipient in topical medicines for dermal application.
2497	HEKLA LAVA	H	Only for use as an active homoeopathic ingredient.
2498	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%.
2499	HELIANTHEMUM NUMMULARIUM	A, H	
2500	HELIANTHUS ANNUUS	A, E, H	
2501	HELIANTHUS TUBEROSUS	A, H	
2502	HELICHRYSUM ANGUSTIFOLIUM	A, E, H	
2503	HELICHRYSUM ARENARIUM	A, H	
2504	HELIOTROPYL 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%.



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2505	HELLEBORUS NIGER	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2506	HELLEBORUS VIRIDIS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2507	HELONIAS RHIZOME DRY	A, H	
2508	HELONIAS RHIZOME POWDER	A, H	
2509	HEMIDESMUS INDICUS	A, E, H	
2510	HEMP SEED OIL	A, E	<p>Only to be used in a medicine where Elixinol Wellness (Byron Bay) Pty Ltd (Client ID 78778), 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 13 December 2024.</p> <p>Cannabidiol and tetrahydrocannabinols are mandatory components of hemp seed oil.</p> <p>The total concentration of cannabidiol in the medicine must not be more than 75 mg/kg.</p> <p>The total concentration of tetrahydrocannabinols in the medicine must not be more than 10 mg/kg.</p> <p>The route of administration for medicines that contain hemp seed oil must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 36 g of hemp seed oil.</p>

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			<p>The following warning statements (or words to that effect) are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- ‘Not for use in children under 2 years of age’; and</li> <li>- ‘Not to be taken on the same day with other products containing hemp seed oil, including food sources’.</li> </ul>
2511	HEPTANAL	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>
2512	HEPTANAL DIMETHYL ACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2513	HEPTANOIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2514	HEPTENAL	E	<p>Permitted for use only in combination with other permitted</p>

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			<p>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>
2515	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>
2516	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>
2517	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 25%.</p>
2518	HERACLEUM HEMSLEYANUM	A, H	
2519	HERNIARIA GLABRA	A, H	
2520	HESPERIDIN	A, E	
2521	HESPEROCYPARIS MACROCARPA	A, H	
2522	HESPEROYUCCA WHIPPLEI	A, H	
2523	HEX-3-ENYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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2524	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%.
2525	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 1%.
2526	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2527	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.
2528	HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			<p>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 than 1%.</p>
2529	HEXANOIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2530	HEXASODIUM FYTATE	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 Hexasodium fytate in the medicine must be no more than 1.0 %.</p>
2531	HEXENAL	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>
2532	HEXYL 2-METHYLBUTYRATE	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</p>

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			medicine must be no more than 1%.
2533	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%.
2534	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 medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2535	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%.
2536	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%.
2537	HEXYL ISOBUTYRATE	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%.
2538	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%.
2539	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2540	HEXYL NICOTINATE	E	
2541	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%.
2542	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%.
2543	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

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			1%.
2544	HEXYLDECANOL	E	<p>Only for use as an excipient in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration of the medicine must be no more than 3%.</p>
2545	HEXYLENE GLYCOL	E	<p>Only for use as an excipient in topical medicines for dermal application.</p>
2546	HEXYLRESORCINOL	A	<p>Permitted for use only in medicated throat lozenges.</p> <p>The medicine of must not contain more than 2.5 mg of hexylresorcinol per lozenge.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 30mg of hexylresorcinol.</p> <p>The medicine label must specify that the medicine is only to be used for 7 days (or less).</p> <p>The following warning statement must be included on the medicine label:</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).</p>
2547	HIBISCUS ESCULENTUS	A, H	
2548	HIBISCUS MUTABILIS	A, H	
2549	HIBISCUS ROSA-SINENSIS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>



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2550	HIBISCUS SABDARIFFA	A, E, H	
2551	HIERACIUM PILOSELLA	A, H	
2552	HIGH AMYLOSE MAIZE STARCH	A, E, H	
2553	HIGH CHROMIUM YEAST	A, E	Chromium is a mandatory component of high chromium yeast. The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic chromium sources. High chromium yeast is considered to be an organic form of chromium.
2554	HIGH FRUCTOSE MAIZE SYRUP	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%.
2555	HIGH MOLYBDENUM YEAST	A, E	Molybdenum is a mandatory component of high molybdenum yeast. The maximum daily dose of molybdenum from high molybdenum yeast must be no more than 62.5 micrograms.
2556	HIGH SELENIUM YEAST	A	When for oral or sublingual use, selenium is a mandatory component of high selenium yeast. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) "This medicine contains selenium which is toxic in high

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			doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
2557	HIMATANTHUS LANCIFOLIUS	A, E, H	
2558	HIPPOPHAE RHAMNOIDES	A, E, H	
2559	HIRSCHFELDIA INCANA	A, H	Allyl isothiocyanate is a mandatory component of <i>Hirschfeldia incana</i> 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%.
2560	HISTAMINE DIHYDROCHLORIDE	H	Only for use as an active homoeopathic ingredient.
2561	HISTIDINE	A	
2562	HISTIDINE HYDROCHLORIDE	A, E, H	
2563	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%.
2564	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 5%.  If used in a fragrance the total

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			fragrance concentration in a medicine must be no more 1%.
2565	HOLCUS LANATUS	A, H	
2566	HOLY THISTLE HERB DRY	A, H	
2567	HOLY THISTLE HERB POWDER	A, H	
2568	HOMALOMENA OCCULTA	A, H	
2569	HOMOSALATE	A, E	<p>For use as an active ingredient only in sunscreens for dermal application.</p> <p>For use as an excipient only in topical medicines for dermal application.</p> <p>Not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 15%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> <li>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</li> </ul>
2570	HONEY	A, E	<p>When the route of administration is oral, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).</li> </ul>
2571	HONEY BEE	H	Only for use as an active homoeopathic ingredient.
2572	HONEY EXTRACT	E	Honey extract must not be included in medicines intended for use in the eye.

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			The concentration of honey extract in the medicine must not be more than 1%.
2573	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%.
2574	HOP STROBILE DRY	A, H	
2575	HOP STROBILE POWDER	A, H	
2576	HOPS OIL	A, E, H	
2577	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.
2578	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.
2579	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 5%.
2580	HOTTONIA PALUSTRIS	A, H	
2581	HOUTTUYNIA CORDATA	A, H	
2582	HOVENIA DULCIS	A, H	
2583	HUMULUS LUPULUS	A, E, H	
2584	HYALURONIC ACID	E	Only for use as an excipient in topical medicines for dermal application.

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2585	HYDNOCARPUS CASTANEUS	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.
2586	HYDRANGEA ARBORESCENS	A, H	
2587	HYDRANGEA PANICULATA	A, H	
2588	HYDRASTIS CANADENSIS	A, E, H	
2589	HYDRATED SILICA	E	Only for use when the route of administration is other than inhalation.
2590	HYDROCHLORIC ACID	E	The concentration of the medicine must be no more than 0.5%.
2591	HYDROCOTYLE UMBELLATA	A, H	
2592	HYDROGEN CYANIDE	H	Only for use as an active homoeopathic ingredient.
2593	HYDROGEN PEROXIDE	A, E	When used as the active ingredient, it is only for use in topical medicines for dermal application. The concentration of hydrogen peroxide in the medicine must be no more than 3%. 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.
2594	HYDROGENATED BUTYLENE/ETHYLENE/STYRENE COPOLYMER	E	Only for use in topical medicines for dermal application. The combined concentration of

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			hydrogenated butylene/ethylene/stryene copolymer and hydrogenated ethylene/propylene/styrene copolymer in the medicine must be no more than 9%.
2595	HYDROGENATED C6-14 OLEFIN POLYMERS	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%.
2596	HYDROGENATED CASTOR OIL	E	
2597	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%.
2598	HYDROGENATED COCONUT OIL	E	
2599	HYDROGENATED COTTONSEED OIL	E	
2600	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.
2601	HYDROGENATED ETHYLENE/PROPYLENE/STYRENE COPOLYMER	E	The combined concentration of hydrogenated ethylene/propylene/styrene copolymer must be no more than 9%.
2602	HYDROGENATED LANOLIN	E	
2603	HYDROGENATED LECITHIN	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2604	HYDROGENATED PALM GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.6%.
2605	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%.
2606	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%.
2607	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.
2608	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.
2609	HYDROGENATED POLYDEXTROSE	A	Only permitted for use in medicines:

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			(a) limited to oral routes of administration; and (b) when the maximum recommended daily dose does not provide more than 15 g of hydrogenated polydextrose.
2610	HYDROGENATED POLYISOBUTENE	E	Only for use in topical medicines for dermal application.
2611	HYDROGENATED SOYA OIL	E	
2612	HYDROGENATED TALLOW GLYCERIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 3%.
2613	HYDROGENATED VEGETABLE OIL	E	
2614	HYDROLIAC	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%.
2615	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%
2616	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%
2617	HYDROLYSED CEREAL SOLIDS	E	Permitted for use only in



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			<p>combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2618	HYDROLYSED CHICKEN CARTILAGE EXTRACT	A	<p>Only to be used in a medicine where BioCell Technology LLC (Client ID 70666), 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 25 October 2023.</p> <p>The route of administration for medicines that contain hydrolysed chicken cartilage extract must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 2000 mg hydrolysed chicken cartilage extract.</p> <p>The following warning statements (or words to the same effect) are required on the medicine label: - (ADULT) 'Adults only'.</p>
2619	HYDROLYSED COLLAGEN	A, E	
2620	HYDROLYSED ELASTIN	E	Only for use in topical medicines for dermal application.
2621	HYDROLYSED GELATIN	A, E	
2622	HYDROLYSED GLYCOSAMINOGLYCANS	E	Only for use in topical medicines for dermal application.
2623	HYDROLYSED JOJOBA ESTERS	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. The concentration in the medicine must be no more than 5%.
2624	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%.
2625	HYDROLYSED MAIZE STARCH	E	
2626	HYDROLYSED MILK PROTEIN	E	
2627	HYDROLYSED RICE	A, E, H	
2628	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%.
2629	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%.
2630	HYDROLYSED VEGETABLE PROTEIN	E	
2631	HYDROLYSED WHEAT PROTEIN	E	Gluten is a mandatory component of hydrolysed wheat protein.
2632	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%.
2633	HYDROLYSED YEAST PROTEIN	E	Only for use in topical medicines for dermal application and not to

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			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%.
2634	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%.
2635	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.
2636	HYDROXOCOBALAMIN	A	
2637	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%.
2638	HYDROXYAPATITE	A, E	
2639	HYDROXYCITRATE COMPLEX	A	Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.

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2640	HYDROXYCITRIC ACID	A	
2641	HYDROXYCITRONELLAL	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>
2642	HYDROXYCITRONELLAL DIMETHYL ACETAL	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>
2643	HYDROXYCITRONELLAL- METHYLANTHRANILATE	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>
2644	HYDROXYCITRONELLOL	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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2645	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%.
2646	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%.
2647	HYDROXYLATED LANOLIN	E	
2648	HYDROXYLATED MILK GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.  The concentration must be no more than 0.1%.
2649	HYDROXYLYSINE	A, E	
2650	HYDROXYMETHYLCELLULOSE	E	
2651	HYDROXYOCTACOSANYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
2652	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%.
2653	HYDROXYPROLINE	A, E	
2654	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

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			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.
2655	HYDROXYPROPYL STARCH	E	
2656	HYDROXYPROPYLBETADEX	E	Only for use in topical medicines for dermal application.
2657	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%.
2658	HYETELLOSE	E	
2659	HYLOCEREUS LEMAIREI	E	Permitted for use only as a colour for oral and topical use.
2660	HYLOCEREUS UNDATUS	A, H	
2661	HYMETELLOSE	E	
2662	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

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			300 micrograms/L or 0.00003%.
2663	HYOSCYAMUS LEAF POWDER	A, H	Alkaloids calculated as hyoscyamine and hyoscyne are mandatory components of Hyoscamus leaf powder. 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 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2664	HYOSCYAMUS NIGER	A, H	Alkaloids calculated as hyoscyamine and hyoscyne are mandatory components of Hyoscyamus niger. The concentration of hyoscyamine in the medicine must be no more than 3 micrograms/kg or 3 micrograms/L or 0.3%. The concentration of hyoscyne in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2665	HYPERICUM ASCYRON	A, H	
2666	HYPERICUM JAPONICUM	A, H	
2667	HYPERICUM PERFORATUM	A, E, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
2668	HYPROLOSE	E	
2669	HYPROMELLOSE	E	

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2670	HYPROMELLOSE PHTHALATE	E	
2671	HYPTIS SUAVEOLENS	A, H	
2672	HYSSOPUS OFFICINALIS	A, E, H	
2673	IBERIS AMARA	A, H	
2674	ICHTHAMMOL	H	Only for use as an active homoeopathic ingredient.
2675	ILEX AQUIFOLIUM	A, H	
2676	ILEX CHINENSIS	A, H	
2677	ILEX PARAGUARIENSIS	A, E, H	<p>Caffeine is a mandatory component of <i>Ilex paraguariensis</i>.</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>When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.</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 1%.</p> <p>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>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> <p>- (ADULT) 'Adults only' (or words to that effect).</p>



			<p>- (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.'</p> <p>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</p> <p>When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <p>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</p> <p>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</p>
2678	ILEX ROTUNDA	A, H	
2679	ILEX VERTICILLATA	A, H	
2680	ILLICIUM 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> <p>(a) the nominal capacity of the container must not be more than 50 millilitres;</p> <p>(b) a restricted flow insert must be fitted on the container; and</p> <p>(c) the following warning statement is required on the label:</p>

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			- (CHILD) 'Keep out of reach of children' (or words to that effect).
2681	IMIDUREA	E	Only for use in topical medicines for dermal application.
2682	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%.
2683	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%.
2684	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%.
2685	IMPATIENS BALSAMINA	A, H	
2686	IMPATIENS GLANDULIFERA	A, H	
2687	IMPERATA CYLINDRICA	A, E, H	
2688	INDIGO CARMINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2689	INDIGO CARMINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2690	INDIGOFERA TINCTORIA	A, H	

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2691	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%.
2692	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.
2693	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%.
2694	INDUSTRIAL METHYLATED SPIRIT	E	
2695	INOSITOL	A, E	
2696	INULA BRITANNICA	A, H	
2697	INULA HELENIUM	A, E, H	
2698	INULA RACEMOSA	A, H	
2699	INULIN	A, E	
2700	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 medicine must be no more than 1.2%.
2701	INVERT SUGAR	E	
2702	INVERT SYRUP	E	When the route of administration is oral or sublingual, glucose is a mandatory component of Invert syrup.

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2703	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>
2704	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>
2705	IONONE	E	<p>Permitted for use only:</p> <p>(a) in topical medicines for dermal application; and</p> <p>(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
2706	IOPAMIDOL	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>
2707	IPECACUANHA DRY	A, H	<p>Emetine is a mandatory component of Ipecacuanha Dry.</p> <p>The concentration of emetine in</p>

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			the medicine must be no more than 0.2%.
2708	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%.
2709	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%.
2710	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 more than 0.2%.
2711	IPOMOEA BATATAS	A, H	
2712	IPOMOEA JALAPA	A, H	
2713	IRIDOPHYCUS FLACCIDUM	A, H	Iodine is a mandatory component of Iridophycus flaccidum. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2714	IRIS DOMESTICA	A, H	
2715	IRIS FLORENTINA	A, H	
2716	IRIS GERMANICA	A, H	

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2717	IRIS PALLIDA	A, H	
2718	IRIS TENAX	H	
2719	IRIS VERSICOLOR	A, H	
2720	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 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>

2721	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> <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>
2722	IRON (II) GLYCINATE	A	<p>Only for use in oral medicines.</p> <p>Iron is a mandatory component of</p>

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iron (II) glycinate.

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.

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:

- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).

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2723

IRON (III) GLYCINATE

A

Only for use in oral medicines.

Iron is a mandatory component of iron (III) glycinate.

When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.

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			<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:          - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2724	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>

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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 containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.

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:

- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).

2725	IRON OXIDE BLACK	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
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			<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>
2726	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>
2727	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>
2728	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</p>

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			<p>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 treatment of iron deficiency conditions' (or words to that effect).</p>
2729	IRONE	E	
2730	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.

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			The concentration must be no more than 0.375%.
2731	ISATIS TINCTORIA	A, H	
2732	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%.
2733	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%.
2734	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2735	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

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

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			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2740	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>
2741	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>
2742	ISOAMYL HEXANOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2743	ISOAMYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a</p>

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			<p>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>
2744	ISOAMYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total 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>
2745	ISOAMYL LAURATE	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration must be no more than 12%.</p>
2746	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</li> </ul>



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			exposed to the sun' (or words to this effect).
2747	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>
2748	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 1%.</p>
2749	ISOAMYL PROPIONATE	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>
2750	ISOAMYL SALICYLATE	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>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2751	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%.
2752	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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2753	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%.
2754	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%.

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2755	ISOBUTANE	E	Only for use in topical medicines for dermal application.
2756	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%.
2757	ISOBUTYL ALCOHOL	E	The residual solvent limit for Isobutyl alcohol is 50mg per recommended daily dose. The concentration of isobutyl alcohol must be no more than 0.5% of the formulation.
2758	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%.
2759	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%.
2760	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

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			medicine must be no more than 5%.
2761	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%.
2762	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%.
2763	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%.
2764	ISOBUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
2765	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2766	ISOBUTYL ISOVALERATE	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2767	ISOBUTYL 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>
2768	ISOBUTYL PROPIONATE	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>
2769	ISOBUTYL QUINOLINE	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>
2770	ISOBUTYL SALICYLATE	E	<p>Only for use in topical medicines for dermal application.</p>
2771	ISOBUTYLENE/ISOPRENE COPOLYMER	E	<p>Only for oral use when the dosage form is chewing gum.</p> <p>The concentration must be consistent with best practice for the production of gum delivery</p>

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			systems.
2772	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%.
2773	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%.
2774	ISOCETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2775	ISOCETYL LINOLEOYL STEARATE	E	Only for use in topical medicines for dermal application.
2776	ISOCETYL STEARATE	E	Only for use in topical medicines for dermal application.
2777	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%.
2778	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

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			medicine must be no more than 1%.
2779	ISODECYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
2780	ISODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2781	ISODECYL OLEATE	E	Only for use in topical medicines for dermal application.
2782	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%.
2783	ISODODECANE	E	Only for use in topical medicines for dermal application.
2784	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%.
2785	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%. When the medicine is for dermal use, the total concentration of isoeugenol in the medicine must

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			not be more than 0.02%.
2786	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%.
2787	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 medicine must be no more than 1%.
2788	ISOHEXADECANE	E	Only for use in topical medicines for dermal application.
2789	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 1%.
2790	ISOLEUCINE	A, E	
2791	ISOMALT	E	
2792	ISOMENTHONE	E	Permitted for use only in combination with other permitted



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			<p>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>
2793	ISOMETHYLIONONE	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>
2794	ISONONYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2795	ISONONYL ISONONANOATE	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.</p> <p>The concentration must be no more than 15%.</p>
2796	ISOPENTANE	E	<p>For dental use only.</p> <p>The concentration must be no more than 2%.</p>
2797	ISOPENTANOIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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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%.
2798	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%. The total concentration of isophorone in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
2799	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%.
2800	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%.
2801	ISOPROPYL 4-	E	Only for use in topical medicines

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	HYDROXYBENZOATE		for dermal application.
2802	ISOPROPYL ACETATE	E	Only for use in topical medicines for dermal application.
2803	ISOPROPYL ALCOHOL	E	
2804	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%.
2805	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%.
2806	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
2807	ISOPROPYL LANOLATE	E	Only for use in topical medicines for dermal application.
2808	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%.
2809	ISOPROPYL MYRISTATE	E	
2810	ISOPROPYL PALMITATE	E	Only for use in topical medicines for dermal application.
2811	ISOPROPYL PPG-2 ISODECETH-7 CARBOXYLATE	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. The concentration must be no more than 10%.
2812	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2813	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%.
2814	ISOPROPYL-3-METHYL-BUTANE THIOATE	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%.
2815	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%.
2816	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%.
2817	ISOSTEARIC ACID	E	Only for use in topical medicines

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			for dermal application.
2818	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%.
2819	ISOSTEARYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2820	ISOSTEARYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2821	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%.
2822	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%.
2823	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%.
2824	ISOVALERIC ACID	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>
2825	ISPAGHULA HUSK DRY	A, H	<p>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>
2826	ISPAGHULA HUSK POWDER	A, H	<p>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>
2827	IVA AXILLARIS	A, H	
2828	JAMAICA DOGWOOD BARK DRY	A, H	
2829	JAMAICA DOGWOOD BARK POWDER	A, H	
2830	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 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2831	JASMINE LACTONE	E	Only for use in topical medicines

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				for dermal application.
2832	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%.
2833	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%.
2834	JASMINUM OFFICINALE	A, E, H		
2835	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%.
2836	JATEORHIZA PALMATA	A, H		
2837	JATROPHA CURCAS	H		Only for use as an active homoeopathic ingredient
2838	JERUSALEM ARTICHOKE	E		
2839	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%.
2840	JUGLANS CINEREA	A, E, H		
2841	JUGLANS NIGRA	A, E, H		
2842	JUGLANS REGIA	A, H		

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2843	JUNCUS EFFUSUS	A, H	
2844	JUNIPER BERRY OIL	A, E, H	
2845	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%.
2846	JUNIPERUS CALIFORNICA	A, H	
2847	JUNIPERUS COMMUNIS	A, E, H	
2848	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%.
2849	JUNIPERUS OXYCEDRUS	A, H	
2850	JUNIPERUS VIRGINIANA	A, E, H	
2851	JUSTICIA ADHATODA	A, H	