

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
2175	FABIANA IMBRICATA	A, H	
2176	FAGOPYRUM ESCULENTUM	A, H	
2177	FAGUS GRANDIFOLIA	A, H	
2178	FAGUS SYLVATICA	A, H	
2179	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%.
2180	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%.
2181	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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2182	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>
2183	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>
2184	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>
2185	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"> - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.'

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2186	FENNEL LEAF	E	
2187	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>
2188	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>

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2189	FENUGREEK	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>
2190	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>
2191	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</p>

			<p>required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2192	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 child resistant closure.</p>

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

			<p>multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2194	FERRIC GLYCEROPHOSPHATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferric glycerophosphate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional</p>

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			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).
2195	FERRIC OXIDE	E	
2196	FERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2197	FERRIC PYROPHOSPHATE	A, H	When for internal use, iron is a mandatory component of ferric pyrophosphate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.

			<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>
2198	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>
2199	FERROSOFERRIC PHOSPHATE	H	<p>Only for use as an active homoeopathic ingredient.</p>
2200	FERROUS FUMARATE	A, H	<p>When for internal use, iron is a mandatory component of ferrous fumarate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p>

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			<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 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 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</p>

			<p>elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2202	FERROUS GLUCONATE DIHYDRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferrous gluconate dihydrate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of</p>

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			<p>elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2203	FERROUS IODIDE	H	Only for use as an active homoeopathic ingredient.
2204	FERROUS LACTATE TRIHYDRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferrous lactate trihydrate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of</p>

			<p>elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2205	FERROUS PHOSPHATE OCTAHYDRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferrous phosphate octahydrate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams</p>

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			<p>of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2206	FERROUS PICRATE	H	Only for use as an active homoeopathic ingredient.
2207	FERROUS SULFATE	A, E, H	<p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are</p>

			<p>required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2208	FERROUS SULFATE HEPTAHYDRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferrous sulfate heptahydrate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <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>

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			<p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2209	FERULA ASSA-FOETIDA	A, E, H	
2210	FERULA FOETIDA	A, E, H	
2211	FERULA GALBANIFLUA	A, E, H	
2212	FERULA RUBRICAULIS	A, E, H	
2213	FERULA SUMBUL	A, H	
2214	FERULIC ACID	E	Only for use in topical medicines for dermal application.
2215	FESTUCA ELATIOR	A, H	
2216	FEVERFEW HERB DRY	A, H	
2217	FEVERFEW HERB POWDER	A, H	
2218	FICUS CARICA	A, E, H	
2219	FICUS PUMILA	A, H	
2220	FIG	E	
2221	FIG DRY	A, H	
2222	FILIPENDULA ULMARIA	A, H	<p>Methyl salicylate is a mandatory component of <i>Filipendula ulmaria</i>.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p>

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
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			<p>sunlight.' (or words to that effect);</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</p> <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> <p>- (IRRIT) 'If irritation develops, discontinue use'.</p>
2223	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>
2224	FIR NEEDLE OIL CANADIAN	A, E	
2225	FIR NEEDLE OIL SIBERIAN	A, E	
2226	FIRMIANA SIMPLEX	A, E, H	
2227	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2228	FLEMINGIA MACROPHYLLA	A, H	
2229	FLOUVE OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2230	FLUORESCEIN SODIUM	E	
2231	FOENICULUM VULGARE	A, E, H	When used in oral medicines, the following warning statements are required on the label:

			<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> <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> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
2232	FOLIC ACID	A	<p>When for internal use, the maximum recommended daily dose must not provide more than 500 micrograms of folic acid.</p> <p>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.</p>
2233	FOOD ORANGE 6	E	Permitted for use only as a colour in medicines limited to

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			topical and oral routes of administration.
2234	FOOD ORANGE 7	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2235	FOOD RED 13	E	Permitted for use only as a colour for topical use.
2236	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%.
2237	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 formic acid. The total concentration of formic acid in the medicine must not be more than 0.5%.
2238	FORSYTHIA SUSPENSIA	A, H	
2239	FORTIFIED WINE	E	Ethanol is a mandatory component of fortified wine.
2240	FRACTIONATED COCONUT OIL	E	
2241	FRACTIONATED PALM KERNEL OIL	A, E	When used as an active ingredient, can only be supplied as an uncompounded

			medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2242	FRAGARIA CHILOENSIS	A, E, H	
2243	FRAGARIA VESCA	A, E, H	
2244	FRAGARIA VIRGINIANA	A, E, H	
2245	FRAGARIA X ANANASSA	A, E, H	
2246	FRANGULA BARK DRY	A, H	<p>Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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]. <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' [or words to that effect]. <p>When not promoted or marketed as laxative, the medicine requires the</p>

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			<p>following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and - (LAX4) 'This product may have laxative effect'. <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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'.
2247	FRANGULA BARK POWDER	A, H	<p>Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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,

			<p>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'.</p>
2248	FRANGULA PURSHIANA	A, H	<p>When for oral use, 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</p>

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 following warning statements on the medicine label:

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

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			- (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
2249	FRAXINUS AMERICANA	A, H	
2250	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A, H	
2251	FRAXINUS EXCELSIOR	A, H	
2252	FRAXINUS ORNUS	A, H	
2253	FRITILLARIA CIRRHOSA	A, H	
2254	FRITILLARIA THUNBERGII	A, H	
2255	FRITILLARIA VERTICILLATA	A, H	
2256	FRUCTOOLIGOSACCHARIDES	A, E	
2257	FRUCTOSE	A, E, H	
2258	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.
2259	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%.
2260	FUMARIA OFFICINALIS	A, E, H	
2261	FUMARIC ACID	E, H	Only for use as an active homoeopathic or excipient ingredient.
2262	FUMITORY HERB DRY	A, H	

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2263	FUMITORY HERB POWDER	A, H	
2264	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%.
2265	FURFURAL	E	Permitted for use only in medicines containing 0.1% or less of furfural and 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 not be more than 5%. If used in a fragrance the total fragrance concentration in a medicine must not be more than 1%.
2266	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%.
2267	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%.
2268	FURFURYL MERCAPTAN	E	Permitted for use only in combination with other permitted ingredients as a flavour.

			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2269	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>
2270	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</p>

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			same effect) is required on the medicine label: (GOS) 'Not to be taken on the same day with other products containing galactooligosaccharides.'
2271	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%.
2272	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%.
2273	GALBANUM RESINOID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2274	GALEGA OFFICINALIS	A, H	
2275	GALEOPSIS SEGETUM	A, H	
2276	GALIUM APARINE	A, H	
2277	GALIUM ODORATUM	A, H	When used as an active ingredient coumarin is a mandatory component of Galium odoratum and the concentration of coumarin in

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			the medicine must be no more than 0.001%.
2278	GALIUM PALUSTRE	A, H	
2279	GALIUM VERUM	A, H	
2280	GALL STONE	H	Only for use as an active homoeopathic ingredient.
2281	GALPHIMIA GLAUCA	A, H	
2282	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%.
2283	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%.
2284	GAMMA-CYCLODEXTRIN	E	
2285	GAMMA-DECALACTONE	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
2286	GAMMA-DODECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2287	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>
2288	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>
2289	GAMMA-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>
2290	GAMMA-LINOLEIC ACID	E	<p>Only for use in topical medicines for dermal application.</p>

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2291	GAMMA-LINOLENIC ACID	E	
2292	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>
2293	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>
2294	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 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>
2295	GAMMA-TERPINENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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2296	GAMMA-TOCOPHEROL	E	
2297	GAMMA-UNDECALACTONE	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>
2298	GAMMA-VALEROLACTONE	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>
2299	GANODERMA LUCIDUM	A, E, H	
2300	GARCINIA GUMMI-GUTTA	A	<p>The requirements specified in paragraphs (a) to (c) below applies to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register before 1 March 2025; and - released for supply before 1 March 2026: <p>(a) Only for use in oral medicines.</p> <p>(b) Must be obtained from the rind of the fruit only.</p> <p>(c) Must not contain any directions for use for children or pregnant or lactating women.</p> <p>The requirements specified in paragraphs (d) to (g) below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2025; or

			<p>- released for supply on or after 1 March 2026:</p> <p>(d) The route of administration for medicines that contain <i>Garcinia gummi-gutta</i> must be limited to oral.</p> <p>(e) The plant part must be limited to fruit peel.</p> <p>(f) The following warning statement is required on the medicine label: ‘In very rare cases, <i>Garcinia gummi-gutta</i> may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.’</p> <p>(g) Medicines containing <i>Garcinia gummi-gutta</i> must not be directed for use in children, or in pregnant or lactating women.</p>
2301	GARCINIA QUAESITA	A, H	<p>The requirements specified below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. <p>When for oral use, the following warning statement is required on the medicine label: ‘In very rare cases, <i>Garcinia quaesita</i> may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.’</p> <p>Medicines containing <i>Garcinia quaesita</i> must not be directed for use in children, or in pregnant or lactating women.</p>
2302	GARDEN BEAN	E	

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2303	GARDENIA JASMINOIDES	A, E	
2304	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%
2305	GARLIC BULB DRY	A, E, H	
2306	GARLIC BULB FRESH	A, H	
2307	GARLIC BULB POWDER	A, E, H	
2308	GARLIC CLOVE POWDER	A, H	
2309	GARLIC OIL	A, E, H	
2310	GASTRODIA ELATA	A, H	
2311	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

			<p>- actuation of the spray device is ergonomically difficult for young children to accomplish. The following warning statement is required on the medicine label:</p> <p>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</p> <p>When for use in topical medicines for dermal application</p> <p>i) the concentration of methyl salicylate in the medicine must not be more than 25%;</p> <p>ii) the following warning statements are required on the medicine label:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</p> <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> <p>- (IRRIT) 'If irritation develops, discontinue use'.</p>
2312	GELATIN	A, E	
2313	GELIDIUM AMANSII	A, H	<p>Iodine is a mandatory component of Gelidium amansii.</p> <p>Only for external use when the concentration of iodine in the</p>

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			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.
2314	GELLAN GUM	E	
2315	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%.
2316	GELSEMIUM POWDER	A, H	
2317	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%.
2318	GENET ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2319	GENTIAN DRY	A, H	
2320	GENTIAN POWDER	A, H	
2321	GENTIANA LUTEA	A, E, H	
2322	GENTIANA MACROPHYLLA	A, H	
2323	GENTIANA RHODANTHA	A, H	
2324	GENTIANA SCABRA	A, H	
2325	GENTIANELLA AMARELLA	A, H	
2326	GERANIAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2327	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%.
2328	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%.
2329	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%.
2330	GERANIUM MACULATUM	A, E, H	
2331	GERANIUM OIL	A, E, H	
2332	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%.

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2333	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%.
2334	GERANIUM ROBERTIANUM	A, E, H	
2335	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%.
2336	GERANIUM SIBIRICUM	A, E, H	
2337	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%.
2338	GERANYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2339	GERANYL BUTYRATE	E	Permitted for use only in combination with other

			<p>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 CROTONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2341	GERANYL ETHYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2342	GERANYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2343	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>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2344	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>
2345	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>
2346	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 fragrance concentration in a medicine must be no more 1%.</p>
2347	GERANYL TIGLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2348	GEUM RIVALE	A, H	

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2349	GEUM URBANUM	A, H	
2350	GHATTI GUM	A, E, H	
2351	GIGARTINA MAMILLOSA	A, H	<p>Iodine is a mandatory component of <i>Gigartina mamilliosa</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>
2352	GINGER DRY	A, E, H	
2353	GINGER OIL	A, E, H	
2354	GINGER OLEORESIN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in the medicine must be no more than 5%.</p>
2355	GINGER POWDER	A, E, H	
2356	GINKGO BILOBA	A, E, H	<p>The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27), as in force or existing from time to time. This condition does not apply to powdered or dried leaf.</p>
2357	GLACIAL ACETIC ACID	E, H	<p>The concentration in the medicine must be no more than 1.5%.</p>
2358	GLECHOMA HEDERACEA	A, H	

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2359	GLECHOMA LONGITUBA	A, H	
2360	GLEDITSIA AUSTRALIS	A, H	
2361	GLEDITSIA SINENSIS	A, H	
2362	GLEHNNIA LITTORALIS	A, H	
2363	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%.
2364	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2365	GLUCONOLACTONE	E	
2366	GLUCOSAMINE HYDROCHLORIDE	A, E	
2367	GLUCOSAMINE SULFATE	A	
2368	GLUCOSAMINE SULFATE POTASSIUM CHLORIDE	A	Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride. When for oral use, only permitted in medicines containing less than 550 milligrams of potassium chloride per dosage unit or in preparations for oral rehydration therapy. 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.'
2369	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	
2370	GLUCOSE	A, E, H	

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2371	GLUCOSE GLUTAMATE	E	Only for use in topical medicines for dermal application.
2372	GLUCOSE MONOHYDRATE	A, E, H	
2373	GLUCOSYLROUTIN	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%.
2374	GLUTAMIC ACID	A, E	Only for use in topical medicines for dermal application.
2375	GLUTAMIC ACID HYDROCHLORIDE	A, E, H	
2376	GLUTAMINE	A, E, H	
2377	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%.
2378	GLUTATHIONE	A, E	When used as an active ingredient, glutathione can only be used in medicines with an oral route of administration and must be indicated for use in adults only and not in pregnant or lactating women. The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (ADULT) 'Adults only' (or words to that effect).

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2379	GLUTEN-FREE WHEAT STARCH	E	
2380	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%.
2381	GLYCEROL	A, E	When used as an active ingredient, it is only for use in topical medicines for dermal application.
2382	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.
2383	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.
2384	GLYCERYL BEHENATE	E	Behenic acid is a mandatory component of glyceryl behenate.

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			<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>
2385	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>
2386	GLYCERYL DIISOSTEARATE	E	<p>For use in topical medicines for dermal application.</p>
2387	GLYCERYL DILAURATE	E	<p>Only for use in topical medicines for dermal application.</p>
2388	GLYCERYL DIOLEATE	E	<p>Only for use in topical medicines for dermal application.</p>
2389	GLYCERYL DISTEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
2390	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>
2391	GLYCERYL ISOSTEARATE	E	<p>Only for use in topical medicines for dermal application and not to be</p>

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5.5%.
2392	GLYCERYL LAURATE	E	Only for use in topical medicines for dermal application.
2393	GLYCERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2394	GLYCERYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2395	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.
2396	GLYCERYL MONOOLEATE	E	
2397	GLYCERYL MONOSTEARATE	E	
2398	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2399	GLYCERYL OLEATE CITRATE	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4% of the formulation.
2400	GLYCERYL PALMITO- STEARATE	E	
2401	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%.
2402	GLYCERYL POLYMETHACRYLATE	E	Only for use in topical medicines for dermal application.
2403	GLYCERYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2404	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.
2405	GLYCERYL SORBITAN OLEOSTEARATE	E	Only for use in topical medicines for dermal application.

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2406	GLYCERYL STARCH	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 4%.</p> <p>The residual levels of epichlorohydrin are to be kept below the level of detection.</p>
2407	GLYCERYL STEARATE CITRATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 5%.</p>
2408	GLYCERYL TRIACETYL HYDROXYSTEARATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 6%.</p>
2409	GLYCERYL TRIACETYL RICINOLEATE	E	<p>Only for use in topical medicines for dermal application.</p>
2410	GLYCERYL TRINITRATE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>The total concentration of glyceryl trinitrate in the medicine must not be more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.</p>
2411	GLYCERYL UNDECYLENATE	E	<p>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%.</p>
2412	GLYCINE	A, E	

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2413	GLYCINE MAX	A, E, H	
2414	GLYCOGEN	E	Only for use in topical medicines for dermal application.
2415	GLYCOL DISTEARATE	E	Only for use in topical medicines for dermal application.
2416	GLYCOLIC ACID	E	<p>Only for use in topical medicines for dermal application.</p> <p>Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When present as an excipient in sunscreens, the concentration in the medicine must be no more than 5%.</p> <p>When used as an excipient ingredient in other medicines the concentration in the medicine must be no more than 20%.</p> <p>If the concentration is more than 5% but no more than 20%, the pH of the medicine must be 3.5 or greater.</p>
2417	GLYCYRRHIZA GLABRA	A, E, H	
2418	GLYCYRRHIZA SPECIES	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2419	GLYCYRRHIZA URALENSIS	A, E, H	
2420	GLYCYRRHIZINIC ACID	E	
2421	GNAPHALIUM AFFINE	A, H	
2422	GNAPHALIUM POLYCEPHALUM	A, H	
2423	GNAPHALIUM ULIGINOSUM	A, H	

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2424	GOAT	H	Only for use as an active homoeopathic ingredient.
2425	GOAT MILK	E	
2426	GOLD	E, H	Only for use as an active homoeopathic or excipient ingredient.
2427	GOLD CHLORIDE	H	Only for use as an active homoeopathic ingredient.
2428	GOLDEN ROD HERB DRY	A, E, H	
2429	GOLDEN SEAL ROOT DRY	A, H	
2430	GOLDEN SEAL ROOT POWDER	A, H	
2431	GOLDEN SYRUP	E	When the route of administration of the medicine is oral or sublingual, sucrose is a mandatory component of golden syrup.
2432	GOMPHRENA GLOBOSA	A, H	
2433	GOSSYPIUM HERBACEUM	A, E, H	
2434	GRAPE	E	
2435	GRAPE SEED OIL	E	
2436	GRAPE WINE RED	E	Ethanol is a mandatory component of grape wine red.
2437	GRAPE WINE SHERRY	E	Ethanol is a mandatory component of grape wine sherry.
2438	GRAPE WINE WHITE	E	Ethanol is a mandatory component of grape wine white.
2439	GRAPEFRUIT	E	
2440	GRAPEFRUIT OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2441	GRAPEFRUIT OIL COLDPRESSED	A, E, H	
2442	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%.
2443	GRAPEFRUIT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2444	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%.
2445	GRAPHITE	H	Only for use as an active homoeopathic ingredient.
2446	GRATIOLA LINIFOLIA	A, H	
2447	GREATER NETTLE HERB DRY	A, H	
2448	GREATER NETTLE HERB POWDER	A, H	
2449	GREATER NETTLE ROOT DRY	A, H	
2450	GREATER NETTLE ROOT POWDER	A, H	

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2451	GREEN LIPPED MUSSEL	A	The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
2452	GREEN LIPPED MUSSEL DRIED	A	The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
2453	GREEN LIPPED MUSSEL OIL	A	The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
2454	GREEN S	E	Only for use as a colour in topical and oral medicines.
2455	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.'
2456	GRINDELIA CAMPORUM	A, H	
2457	GRINDELIA ROBUSTA	A, H	
2458	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%.
2459	GROUND IVY HERB DRY	A, H	
2460	GROUND IVY HERB POWDER	A, H	

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2461	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%.
2462	GUAIACOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
2463	GUAIACUM OFFICINALE	A, E, H	
2464	GUAIACUM RESIN	A, E, H	
2465	GUAIACUM SANCTUM	A, H	
2466	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%.
2467	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%.
2468	GUANINE	E	Only for use as an excipient in topical medicines for dermal application.

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2469	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.
2470	GUAR GALACTOMANNAN	A	When for oral use: (a) the maximum daily dose must provide no more than 25 g of guar galactomannan; (b) the medicine requires the following dosage instructions: - (FIBRE) 'The dose of fibre should be increased gradually. Fluid intake should be increased with an increasing dose of fibre.' (or words to that effect) (c) when the dosage form is a powder preparation, the medicine requires the following dosage instructions: - (DNTPOW) 'Do not take powder alone. Mix with food or fluid.' (or words to that effect).
2471	GUAR GUM	A, E, H	
2472	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	E	Only for use as an excipient in topical medicines for dermal application.
2473	GUAREA RUSBYI	A, H	
2474	GUAVA	E	
2475	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%.
2476	GYMNADENIA NIGRA	A	

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2477	GYMNEMA SYLVESTRE	A, H	
2478	GYMNOCLADUS DIOICA	A, H	
2479	GYNOSTEMMA PENTAPHYLLUM	A	The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).
2480	HAHNEMANN'S SOLUBLE MERCURY	H	Only for use as an active homoeopathic ingredient.
2481	HALIBUT-LIVER OIL	A, E	<p>Colecalciferol and Vitamin A are mandatory components of Halibut-liver oil.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not 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.</p> <p>- (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this</p>

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			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.'
2482	HAMAMELIS LEAF DRY	A, H	
2483	HAMAMELIS LEAF POWDER	A, H	
2484	HAMAMELIS VIRGINIANA	A, E, H	
2485	HAMAMELIS WATER	A, E, H	
2486	HANDROANTHUS HEPTAPHYLLUS	A, H	
2487	HANDROANTHUS IMPETIGINOSUS	A, E, H	
2488	HARD FAT	E	
2489	HARD PARAFFIN	E	
2490	HARICOT BEAN	E	
2491	HARPAGOPHYTUM PROCUMBENS	A, E, H	
2492	HARUNGANA MADAGASCARIENSIS	A, H	
2493	HAZEL NUT	E	
2494	HAZEL NUT OIL	E	
2495	HEAVY KAOLIN	E	
2496	HEAVY MAGNESIUM OXIDE	A, E, H	Magnesium is a mandatory component of heavy magnesium oxide. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total

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			<p>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 directed for use in infants younger than 12 months of age.</p>
2497	HECTORITE	E	Only for use in topical medicines for dermal application.
2498	HEDEOMA PULEGIOIDES	A	
2499	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%.
2500	HEDTA	E	Only for use as an excipient in topical medicines for dermal application.
2501	HEKLA LAVA	H	Only for use as an active homoeopathic ingredient.
2502	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%.

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2503	HELIANTHEMUM NUMMULARIUM	A, H	
2504	HELIANTHUS ANNUUS	A, E, H	
2505	HELIANTHUS TUBEROSUS	A, H	
2506	HELICHRYSUM ANGUSTIFOLIUM	A, E, H	
2507	HELICHRYSUM ARENARIUM	A, H	
2508	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%.
2509	HELLEBORUS NIGER	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2510	HELLEBORUS VIRIDIS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2511	HELONIAS RHIZOME DRY	A, H	
2512	HELONIAS RHIZOME POWDER	A, H	
2513	HEMIDESMUS INDICUS	A, E, H	
2514	HEMP SEED OIL	A, E	Cannabidiol and tetrahydrocannabinols are mandatory components of hemp seed oil. The total concentration of cannabidiol in hemp seed oil must not be more than 75 mg/kg. The total concentration of tetrahydrocannabinols in hemp seed oil must not be more than 10 mg/kg. The route of administration for medicines that contain hemp seed oil must be limited to oral. The maximum recommended daily dose of the medicine

			<p>must not provide more than 36 g of hemp seed oil.</p> <p>The following warning statements (or words to that effect) are required on the medicine label:</p> <ul style="list-style-type: none"> - ‘Not for use in children under 2 years of age’; and - ‘Not to be taken on the same day with other products containing hemp seed oil, including food sources’.
2515	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>
2516	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>
2517	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>
2518	HEPTENAL	E	<p>Permitted for use only in combination with other</p>

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			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2519	HEPTYL 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%.
2520	HEPTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2521	HEPTYL UNDECYLENATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of the medicine must be no more than 25%.
2522	HERACLEUM HEMSLEYANUM	A, H	
2523	HERNIARIA GLABRA	A, H	
2524	HESPERIDIN	A, E	
2525	HESPEROCYPARIS MACROCARPA	A, H	
2526	HESPEROYUCCA WHIPPLEI	A, H	
2527	HEX-3-ENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
2528	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%.
2529	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%.
2530	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%.
2531	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.
2532	HEXANOATE	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2533	HEXANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2534	HEXASODIUM FYTATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of Hexasodium fytate in the medicine must be no more than 1.0 %.
2535	HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2536	HEXYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2537	HEXYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2538	HEXYL BUTYRATE	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>
2539	HEXYL CAPROATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2540	HEXYL FORMATE	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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2541	HEXYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2542	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%.
2543	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2544	HEXYL NICOTINATE	E	
2545	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%.
2546	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%.
2547	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

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			medicine must be no more than 1%.
2548	HEXYLDECANOL	E	Only for use as an excipient in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration of the medicine must be no more than 3%.
2549	HEXYLENE GLYCOL	E	Only for use as an excipient in topical medicines for dermal application.
2550	HEXYLRESORCINOL	A	Permitted for use only in medicated throat lozenges. The medicine of must not contain more than 2.5 mg of hexylresorcinol per lozenge. The maximum recommended daily dose of the medicine must not provide more than 30mg of hexylresorcinol. The medicine label must specify that the medicine is only to be used for 7 days (or less). The following warning statement must be included on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
2551	HIBISCUS ESCULENTUS	A, H	
2552	HIBISCUS MUTABILIS	A, H	
2553	HIBISCUS ROSA-SINENSIS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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2554	HIBISCUS SABDARIFFA	A, E, H	
2555	HIERACIUM PILOSELLA	A, H	
2556	HIGH AMYLOSE MAIZE STARCH	A, E, H	
2557	HIGH CHROMIUM YEAST	A, E	<p>Chromium is a mandatory component of high chromium yeast.</p> <p>The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic chromium sources.</p> <p>High chromium yeast is considered to be an organic form of chromium.</p>
2558	HIGH FRUCTOSE MAIZE SYRUP	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2559	HIGH MOLYBDENUM YEAST	A, E	<p>Molybdenum is a mandatory component of high molybdenum yeast.</p> <p>The maximum daily dose of molybdenum from high molybdenum yeast must be no more than 62.5 micrograms.</p>
2560	HIGH SELENIUM YEAST	A	<p>When for oral or sublingual use, selenium is a mandatory component of high selenium yeast.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p>

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			- (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
2561	HIMATANTHUS LANCIFOLIUS	A, E, H	
2562	HIPPOPHAE RHAMNOIDES	A, E, H	
2563	HIRSCHFELDIA INCANA	A, H	Allyl isothiocyanate is a mandatory component of Hirschfeldia incana when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
2564	HISTAMINE DIHYDROCHLORIDE	H	Only for use as an active homoeopathic ingredient.
2565	HISTIDINE	A	
2566	HISTIDINE HYDROCHLORIDE	A, E, H	
2567	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%.
2568	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%.

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				If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2569	HOLCUS LANATUS	A, H		
2570	HOLY THISTLE HERB DRY	A, H		
2571	HOLY THISTLE HERB POWDER	A, H		
2572	HOMALOMENA OCCULTA	A, H		
2573	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"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2574	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"> - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).
2575	HONEY BEE	H		Only for use as an active homoeopathic ingredient.
2576	HONEY EXTRACT	E		Honey extract must not be included in medicines intended for use in the eye.

			The concentration of honey extract in the medicine must not be more than 1%.
2577	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%.
2578	HOP STROBILE DRY	A, H	
2579	HOP STROBILE POWDER	A, H	
2580	HOPS OIL	A, E, H	
2581	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.
2582	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.
2583	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%.
2584	HOTTONIA PALUSTRIS	A, H	
2585	HOUTTUYNIA CORDATA	A, H	
2586	HOVENIA DULCIS	A, H	
2587	HUMULUS LUPULUS	A, E, H	
2588	HYALURONIC ACID	E	Only for use as an excipient in topical medicines for dermal application.

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2589	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.
2590	HYDRANGEA ARBORESCENS	A, H	
2591	HYDRANGEA PANICULATA	A, H	
2592	HYDRASTIS CANADENSIS	A, E, H	
2593	HYDRATED SILICA	E	Only for use when the route of administration is other than inhalation.
2594	HYDROCHLORIC ACID	E	The concentration of the medicine must be no more than 0.5%.
2595	HYDROCOTYLE UMBELLATA	A, H	
2596	HYDROGEN CYANIDE	H	Only for use as an active homoeopathic ingredient.
2597	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.
2598	HYDROGENATED BUTYLENE/ETHYLENE/STYRENE COPOLYMER	E	Only for use in topical medicines for dermal application. The combined concentration of hydrogenated butylene/ethylene/styrene

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			copolymer and hydrogenated ethylene/propylene/styrene copolymer in the medicine must be no more than 9%.
2599	HYDROGENATED C6-14 OLEFIN POLYMERS	E	<p>Only permitted for use in solid or semi-solid medicines for dermal application or in topical medicines for dermal application:</p> <p>(a) containing 25% or less of hydrocarbons, liquid; or</p> <p>(b) when packed in pressurised spray packs; or</p> <p>(c) when packed in containers with a capacity of 2 millilitres or less.</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 7%.</p>
2600	HYDROGENATED CASTOR OIL	E	
2601	HYDROGENATED COCO-GLYCERIDES	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 in the medicine must be no more than 3%.</p>
2602	HYDROGENATED COCONUT OIL	E	
2603	HYDROGENATED COTTONSEED OIL	E	
2604	HYDROGENATED DIMER DILINOLEYL/DIMETHYLCARBONATE COPOLYMER	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 in the medicine must be no more than 4% in the product.</p>

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2605	HYDROGENATED ETHYLENE/PROPYLENE/STYRE NE COPOLYMER	E	The combined concentration of hydrogenated ethylene/propylene/styrene copolymer must be no more than 9%.
2606	HYDROGENATED LANOLIN	E	
2607	HYDROGENATED LECITHIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2608	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%.
2609	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%.
2610	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%.
2611	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.

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			<p>The concentration in the medicine must be no more than 2%.</p> <p>Polycyclic aromatic hydrocarbons must be kept below the level of detection.</p>
2612	HYDROGENATED POLYDECENE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p>
2613	HYDROGENATED POLYDEXTROSE	A	<p>Only permitted for use in medicines:</p> <p>(a) limited to oral routes of administration; and</p> <p>(b) when the maximum recommended daily dose does not provide more than 15 g of hydrogenated polydextrose.</p>
2614	HYDROGENATED POLYISOBUTENE	E	<p>Only for use in topical medicines for dermal application.</p>
2615	HYDROGENATED SOYA OIL	E	
2616	HYDROGENATED TALLOW GLYCERIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p>
2617	HYDROGENATED VEGETABLE OIL	E	
2618	HYDROLIAC	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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2619	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%
2620	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%
2621	HYDROLYSED CEREAL SOLIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2622	HYDROLYSED CHICKEN CARTILAGE EXTRACT	A	The route of administration for medicines that contain hydrolysed chicken cartilage extract must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 2000 mg hydrolysed chicken cartilage extract. The following warning statement (or words to the same effect) is required on the medicine label: - (ADULT) 'Adults only'.
2623	HYDROLYSED COLLAGEN	A, E	
2624	HYDROLYSED ELASTIN	E	Only for use in topical medicines for dermal application.

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2625	HYDROLYSED GELATIN	A, E	
2626	HYDROLYSED GLYCOSAMINOGLYCANS	E	Only for use in topical medicines for dermal application.
2627	HYDROLYSED JOJOBA ESTERS	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2628	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%.
2629	HYDROLYSED MAIZE STARCH	E	
2630	HYDROLYSED MILK PROTEIN	E	
2631	HYDROLYSED RICE	A, E, H	
2632	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%.
2633	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%.
2634	HYDROLYSED VEGETABLE PROTEIN	E	

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2635	HYDROLYSED WHEAT PROTEIN	E	Gluten is a mandatory component of hydrolysed wheat protein.
2636	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%.
2637	HYDROLYSED YEAST PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
2638	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%.
2639	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.
2640	HYDROXOCOBALAMIN	A	

2641	HYDROXYACETOPHENONE	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 in the medicine must be no more than 1%.</p>
2642	HYDROXYAPATITE	A, E	
2643	HYDROXYCITRATE COMPLEX	A	<p>The requirements specified in paragraph (a) below applies to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register before 1 March 2025; and - released for supply before 1 March 2026: <p>(a) Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.</p> <p>The requirements specified in paragraphs (b) to (d) below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. <p>(b) Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.</p> <p>(c) When for oral use, the following warning statement is required on the medicine label: 'In very rare cases, hydroxycitrate complex may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.'</p>

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			(d) Medicines containing hydroxycitrate complex must not be directed for use in children, or in pregnant or lactating women.
2644	HYDROXYCITRIC ACID	A	<p>The requirements specified below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. <p>When for oral use, the following warning statement is required on the medicine label:</p> <p>‘In very rare cases, hydroxycitric acid may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.’</p> <p>Medicines containing hydroxycitric acid must not be directed for use in children, or in pregnant or lactating women.</p>
2645	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>
2646	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</p>

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2647	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>
2648	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>
2649	HYDROXYETHYL CETEARAMIDOPROPYLDIMONIUM CHLORIDE	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 in the medicine must be no more than 0.1%.</p>
2650	HYDROXYETHYL UREA	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 1%.</p>
2651	HYDROXYLATED LANOLIN	E	
2652	HYDROXYLATED MILK GLYCERIDES	E	Only for use in topical medicines for dermal

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			application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 0.1%.
2653	HYDROXYLYSINE	A, E	
2654	HYDROXYMETHYLCELLULOSE	E	
2655	HYDROXYOCTACOSANYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
2656	HYDROXYPALMITOYL SPHINGANINE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 0.1%.
2657	HYDROXYPROLINE	A, E	
2658	HYDROXYPROPYL DISTARCH PHOSPHATE	E	Only permitted for: - use in topical medicines for dermal application; and - medicines for internal use. When for use in topical medicines for dermal application: - not to be included medicines intended for use in the eye or damaged skin; and - the concentration of hydroxypropyl distarch phosphate in the medicine must be no more than 4%. When for internal use, the maximum recommended daily dose must not contain more than 240mg of hydroxypropyl distarch phosphate.
2659	HYDROXYPROPYL STARCH	E	
2660	HYDROXYPROPYLBETADEX	E	Only for use in topical medicines for dermal application.

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2661	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%.
2662	HYETELLOSE	E	
2663	HYLOCEREUS LEMAIREI	E	Permitted for use only as a colour for oral and topical use.
2664	HYLOCEREUS UNDATUS	A, H	
2665	HYMETELLOSE	E	
2666	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 not be more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of hyoscyne in the medicine must not be more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2667	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%.

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2668	HYOSCYAMUS NIGER	A, H	Alkaloids calculated as hyoscyamine and hyoscyne are mandatory components of <i>Hyoscyamus niger</i> . 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%.
2669	HYPERICUM ASCYRON	A, H	
2670	HYPERICUM JAPONICUM	A, H	
2671	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.'
2672	HYPROLOSE	E	
2673	HYPROMELLOSE	E	
2674	HYPROMELLOSE PHTHALATE	E	
2675	HYPTIS SUAVEOLENS	A, H	
2676	HYSSOPUS OFFICINALIS	A, E, H	
2677	IBERIS AMARA	A, H	
2678	ICHTHAMMOL	H	Only for use as an active homoeopathic ingredient.
2679	ILEX AQUIFOLIUM	A, H	
2680	ILEX CHINENSIS	A, H	
2681	ILEX PARAGUARIENSIS	A, E, H	Caffeine is a mandatory component of <i>Ilex paraguariensis</i> . 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%.

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.

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%.

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.

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:

- (ADULT) 'Adults only' (or words to that effect).
- (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.'
- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

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

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			<p>warning statements are required on the label:</p> <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
2682	ILEX ROTUNDA	A, H	
2683	ILEX VERTICILLATA	A, H	
2684	ILLICIAM VERUM	A, H	<p>When the plant preparation is oil or distillate, and the concentration of Illicium verum oil or distillate in the preparation is greater than 50%:</p> <ul style="list-style-type: none"> (a) the nominal capacity of the container must not be more than 50 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label: <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect).
2685	IMIDUREA	E	Only for use in topical medicines for dermal application.
2686	IMMORTELLE	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>
2687	IMMORTELLE OIL	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2688	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%.
2689	IMPATIENS BALSAMINA	A, H	
2690	IMPATIENS GLANDULIFERA	A, H	
2691	IMPERATA CYLINDRICA	A, E, H	
2692	INDIGO CARMINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2693	INDIGO CARMINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2694	INDIGOFERA TINCTORIA	A, H	
2695	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%.
2696	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.

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2697	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%.
2698	INDUSTRIAL METHYLATED SPIRIT	E	
2699	INOSITOL	A, E	
2700	INULA BRITANNICA	A, H	
2701	INULA HELENIUM	A, E, H	
2702	INULA RACEMOSA	A, H	
2703	INULIN	A, E	
2704	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%.
2705	INVERT SUGAR	E	
2706	INVERT SYRUP	E	When the route of administration is oral or sublingual, glucose is a mandatory component of Invert syrup.
2707	IODINE	H	Only for use as an active homeopathic ingredient. 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.

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2708	IODOPROPYNYL BUTYLCARBAMATE	E	For use as an excipient ingredient in topical medicines only. The concentration in aqueous medicines must be no more than 10%.
2709	IONONE	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%.
2710	IOPAMIDOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2711	IPECACUANHA DRY	A, H	Emetine is a mandatory component of Ipecacuanha Dry. The concentration of emetine in the medicine must be no more than 0.2%.
2712	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%.
2713	IPECACUANHA PREPARED	A, H	Emetine is a mandatory component of Ipecacuanha Prepared.

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			The concentration of emetine in the medicine must be no more than 0.2%.
2714	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%.
2715	IPOMOEA BATATAS	A, H	
2716	IPOMOEA JALAPA	A, H	
2717	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.
2718	IRIS DOMESTICA	A, H	
2719	IRIS FLORENTINA	A, H	
2720	IRIS GERMANICA	A, H	
2721	IRIS PALLIDA	A, H	
2722	IRIS TENAX	H	
2723	IRIS VERSICOLOR	A, H	
2724	IRON	A, H	Only for use in oral medicines. When used as an active ingredient, 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

		<p>more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 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>
2725	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</p>

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			<p>more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2726	IRON (II) GLYCINATE	A	<p>Only for use in oral medicines.</p> <p>Iron is a mandatory component of iron (II) glycinate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no 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</p>

			<p>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>
2727	IRON (III) GLYCINATE	A	<p>Only for use in oral medicines.</p> <p>Iron is a mandatory component of iron (III) glycinate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when 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</p>

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			<p>contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the 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>
2728	IRON AMINO ACID CHELATE	A, H	<p>Only for use in oral medicines.</p> <p>When used internally, iron is a mandatory component of iron amino acid chelate.</p> <p>The concentration of iron in iron amino acid chelate must be no more than 25%.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p>

			<p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are 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	IRON OXIDE BLACK	E	<p>Permitted for use only as a colour in medicines limited to topical and oral routes of administration.</p> <p>When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.</p>
2730	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</p>

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			medicine must be no more than 10 mg per dosage unit.
2731	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>
2732	IRON PHOSPHATE	A, E, H	<p>When used internally, iron is a mandatory component of iron phosphate and must be declared.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p>

			<p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2733	IRONE	E	
2734	IRVINGIA GABONENSIS SEED TRIGLYCERIDES	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration must be no more than 0.375%.</p>
2735	ISATIS TINCTORIA	A, H	
2736	ISOAMBRETTOLIDE	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>
2737	ISOAMYL 2-METHYLBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a</p>

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			medicine must be no more than 5%.
2738	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%.
2739	ISOAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2740	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%.
2741	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%.
2742	ISOAMYL CAPRYLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2743	ISOAMYL CINNAMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2744	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>
2745	ISOAMYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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2746	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>
2747	ISOAMYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2748	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>
2749	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>
2750	ISOAMYL METHOXYCINNAMATE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to</p>

			<p>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"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2751	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>
2752	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>
2753	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>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2754	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> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2755	ISOBERGAMIATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2756	ISOBORNEOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2757	ISOBORNYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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2758	ISOBORNYL CYCLOHEXANOL	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>
2759	ISOBUTANE	E	<p>Only for use in topical medicines for dermal application.</p>
2760	ISOBUTYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2761	ISOBUTYL ALCOHOL	E	<p>The residual solvent limit for Isobutyl alcohol is 50mg per recommended daily dose.</p> <p>The concentration of isobutyl alcohol must be no more than 0.5% of the formulation.</p>
2762	ISOBUTYL BENZOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2763	ISOBUTYL BENZYL CARBINOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p>

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			If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
2764	ISOBUTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2765	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%.
2766	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%.
2767	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%.
2768	ISOBUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
2769	ISOBUTYL ISOBUTYRATE	E	Permitted for use only in combination with other

			<p>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>
2770	ISOBUTYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2771	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>
2772	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>
2773	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>

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2774	ISOBUTYL SALICYLATE	E	Only for use in topical medicines for dermal application.
2775	ISOBUTYLENE/ISOPRENE COPOLYMER	E	Only for oral use when the dosage form is chewing gum. The concentration must be consistent with best practice for the production of gum delivery systems.
2776	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%.
2777	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%.
2778	ISOCETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2779	ISOCETYL LINOLEOYL STEARATE	E	Only for use in topical medicines for dermal application.
2780	ISOCETYL STEARATE	E	Only for use in topical medicines for dermal application.
2781	ISOCETYL STEAROYL STEARATE	E	Only for use in topical medicines for dermal

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			application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 10%.
2782	ISOCYCLOCITRAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2783	ISODECYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
2784	ISODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2785	ISODECYL OLEATE	E	Only for use in topical medicines for dermal application.
2786	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%.
2787	ISODODECANE	E	Only for use in topical medicines for dermal application.
2788	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%.

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2789	ISOEUGENOL	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> <p>When the medicine is for dermal use, the total concentration of isoeugenol in the medicine must not be more than 0.02%.</p>
2790	ISOEUGENYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2791	ISOEUGENYL BENZYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2792	ISOHEXADECANE	E	<p>Only for use in topical medicines for dermal application.</p>
2793	ISOJASMONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance</p>

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			<p>proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must not be more than 5%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.</p>
2794	ISOLEUCINE	A, E	
2795	ISOMALT	E	
2796	ISOMENTHONE	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 than 1%.</p>
2797	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>
2798	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>
2799	ISONONYL ISONONANOATE	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines</p>

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			intended for use in the eye or on damaged skin. The concentration must be no more than 15%.
2800	ISOPENTANE	E	For dental use only. The concentration must be no more than 2%.
2801	ISOPENTANOIC 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%.
2802	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%.
2803	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%.
2804	ISOPROPYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2805	ISOPROPYL 4-HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
2806	ISOPROPYL ACETATE	E	Only for use in topical medicines for dermal application.
2807	ISOPROPYL ALCOHOL	E	
2808	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%.
2809	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%.
2810	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
2811	ISOPROPYL LANOLATE	E	Only for use in topical medicines for dermal application.
2812	ISOPROPYL LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal

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			application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 5.6%.
2813	ISOPROPYL MYRISTATE	E	
2814	ISOPROPYL PALMITATE	E	Only for use in topical medicines for dermal application.
2815	ISOPROPYL PPG-2 ISODECETH-7 CARBOXYLATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 10%.
2816	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2817	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%.
2818	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%.
2819	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

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2820	ISORALDEINE 70	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>
2821	ISOSTEARIC ACID	E	<p>Only for use in topical medicines for dermal application.</p>
2822	ISOSTEAROYL HYDROLYSED COLLAGEN	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 must be no more than 0.3%.</p>
2823	ISOSTEARYL ALCOHOL	E	<p>Only for use in topical medicines for dermal application.</p>
2824	ISOSTEARYL NEOPENTANOATE	E	<p>Only for use in topical medicines for dermal application.</p>
2825	ISOSTEARYL PALMITATE	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 must be no more than 2%.</p>
2826	ISOTRIDECYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2827	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%.
2828	ISOVALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2829	ISPAGHULA HUSK DRY	A, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
2830	ISPAGHULA HUSK POWDER	A, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
2831	IVA AXILLARIS	A, H	

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2832	JAMAICA DOGWOOD BARK DRY	A, H	
2833	JAMAICA DOGWOOD BARK POWDER	A, H	
2834	JASMINE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2835	JASMINE LACTONE	E	Only for use in topical medicines for dermal application.
2836	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%.
2837	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%.
2838	JASMINUM OFFICINALE	A, E, H	
2839	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%.

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2840	JATEORHIZA PALMATA	A, H	
2841	JATROPHA CURCAS	H	Only for use as an active homoeopathic ingredient
2842	JERUSALEM ARTICHOKE	E	
2843	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%.
2844	JUGLANS CINEREA	A, E, H	
2845	JUGLANS NIGRA	A, E, H	
2846	JUGLANS REGIA	A, H	
2847	JUNCUS EFFUSUS	A, H	
2848	JUNIPER BERRY OIL	A, E, H	
2849	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%.
2850	JUNIPERUS CALIFORNICA	A, H	
2851	JUNIPERUS COMMUNIS	A, E, H	
2852	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%.
2853	JUNIPERUS OXYCEDRUS	A, H	
2854	JUNIPERUS VIRGINIANA	A, E, H	
2855	JUSTICIA ADHATODA	A, H	