Note: See sections 5, 6 and 6A.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient Name	Purpose	Specific requirements
2176	FABIANA IMBRICATA	A, H	
2177	FAGOPYRUM ESCULENTUM	A, H	
2178	FAGUS GRANDIFOLIA	A, H	
2179	FAGUS SYLVATICA	A, H	
2180	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%.
2181	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 b no more than 5%.
			When used in a fragrance, the tot fragrance proprietary excipient formulation in a medicine must b no more than 1%.

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

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2182	FAST GREEN FCF	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2183	FENCHONE	Е	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%.
2184	FENCHYL ACETATE	Е	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%.
2185	FENCHYL ALCOHOL	Е	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%.
2186	FENNEL BITTER SEED DRY	A, E, H	When used in oral medicines, the following warning statements are required on the label:
			- (CHILD3) 'Use in children under 12 years is not recommended'

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

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			<ul> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'</li> </ul>
			- (BREASF) 'Do not use while breastfeeding.'
2187	FENNEL LEAF	E	
2188	FENNEL OIL	A, E, H	Methyl chavicol is a mandatory component of fennel oil.
			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:
			- (CHILD) 'Keep out of reach of children (or words to that effect).'
			The maximum daily dose must provide no more than 150 mg of fennel oil.
			When used in oral medicines, the following warning statements are required on the label:
			- (CHILD3) 'Use in children under 12 years is not recommended.'
			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect).'
			- (BREASF) 'Do not use while breastfeeding.'
2189	FENNEL SWEET SEED DRY	A, E, H	When used in oral medicines, the following warning statements are required on the label:
			- (CHILD3) 'Use in children under 12 years is not recommended'
			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'

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			- (BREASF) 'Do not use while breastfeeding.'
2190	FENUGREEK	Е	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%.
2191	FENUGREEK OIL	E	Fenugreek oil is permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2192	FERRIC AMMONIUM CITRATE	A, E, H	When for internal use, iron is a mandatory component of ferric ammonium citrate.
			When for internal use, the medicine must contain a daily dose of no more than 24 mg of 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

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required to have a child resistant closure.

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

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:

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

2193 FERRIC CHLORIDE

A, E, H

When for internal use, iron is a mandatory component of ferric chloride.

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

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required to have a child resistant closure.

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

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:

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

# 2194 FERRIC CHLORIDE HEXAHYDRATE

A, E, H

When for internal use, iron is a mandatory component of ferric chloride hexahydrate.

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

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

required to have a child resistant closure.

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

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:

- (IRONDEF) 'Not for the

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

## 2195 FERRIC GLYCEROPHOSPHATE A, E, H

When for internal use, iron is a mandatory component of ferric glycerophosphate.

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

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			required to have a child resistant closure.
			Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.
			When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:
			<ul> <li>(IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</li> </ul>
2196	FERRIC OXIDE	Е	
2197	FERRIC PHOSPHATE	Н	Only for use as an active homoeopathic ingredient.
2198	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%).

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			Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.  Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.
			When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:  - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2199	FERROSOFERRIC OXIDE	Е	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.
			When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.
2200	FERROSOFERRIC PHOSPHATE	Н	Only for use as an active homoeopathic ingredient.
2201	FERROUS FUMARATE	A, H	When for internal use, iron is a mandatory component of ferrous fumarate.
			When used as an active ingredient, the medicine must contain a daily

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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 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.

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.

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).

2202 FERROUS GLUCONATE

A, E, H

When for internal use, iron is a mandatory component of ferrous gluconate.

When for internal use, the medicine must contain a daily

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dose of no more than 24 mg of iron.

If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.

In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).

Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.

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

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:

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

2203

FERROUS GLUCONATE DIHYDRATE

A, E, H

When for internal use, iron is a mandatory component of ferrous gluconate dihydrate.

When for internal use, the

medicine must contain a daily

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dose of no more than 24 mg of iron.

If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.

In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).

Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.

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

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:

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

2204

FERROUS IODIDE

Η

Only for use as an active homoeopathic ingredient.

2205 FERROUS LACTATE TRIHYDRATE

A, E, H

When for internal use, iron is a mandatory component of ferrous lactate trihydrate.

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 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 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.

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.

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).

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2206 FERROUS PHOSPHATE OCTAHYDRATE

A, E, H

When for internal use, iron is a mandatory component of ferrous phosphate octahydrate.

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 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 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.

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.

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).

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

			Volume 3
2207	FERROUS PICRATE	Н	Only for use as an active homoeopathic ingredient.
2208	FERROUS SULFATE	A, E, H	When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.
			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 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.
			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.
			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).

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2209 FERROUS SULFATE HEPTAHYDRATE A, E, H

When for internal use, iron is a mandatory component of ferrous sulfate heptahydrate.

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

If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.

In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).

Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.

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

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:

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

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2210	FERULA ASSA-FOETIDA	A, E, H	
2211	FERULA FOETIDA	A, E, H	
2212	FERULA GALBANIFLUA	A, E, H	
2213	FERULA RUBRICAULIS	A, E, H	
2214	FERULA SUMBUL	A, H	
2215	FERULIC ACID	E	Only for use in topical medicines for dermal application.
2216	FESTUCA ELATIOR	A, H	
2217	FEVERFEW HERB DRY	A, H	
2218	FEVERFEW HERB POWDER	A, H	
2219	FICUS CARICA	A, E, H	
2220	FICUS PUMILA	A, H	
2221	FIG	Е	
2222	FIG DRY	A, H	
2223	FILIPENDULA ULMARIA	A, H	Methyl salicylate is a mandatory component of Filipendula ulmaria.  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

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form is spray, the medicine does not require child resistant packaging if:

- the delivery device is engaged into the container in such a way that prevents it from being readily removed;
- direct suction through the delivery device results in delivery of no more than one dosage unit;
   and
- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).
- When for use in topical medicines for dermal application:
- i) the concentration of methyl salicylate in the medicine must not be more than 25%;
- ii) the following warning statements are required on the medicine label:
- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);
- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';
- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);
- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);
- iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:

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			- (IRRIT) 'If irritation develops, discontinue use'.
2224	FIR BALSAM ABSOLUTE	Е	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%.
2225	FIR NEEDLE OIL CANADIAN	A, E	
2226	FIR NEEDLE OIL SIBERIAN	A, E	
2227	FIRMIANA SIMPLEX	A, E, H	
2228	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2229	FLEMINGIA MACROPHYLLA	A, H	
2230	FLOUVE OIL	Е	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%.
2231	FLUORESCEIN SODIUM	E	
2232	FOENICULUM VULGARE	A, E, H	When used in oral medicines, the following warning statements are required on the label:
			- (CHILD3) 'Use in children under 12 years is not recommended'

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

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			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.'
			When the plant preparation is oil or distillate, methyl chavicol is a mandatory component and the maximum daily dose must provide no more than 150 mg of the plant preparation.
			When the plant preparation is oil or distillate and the concentration of methyl 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:
			- (CHILD) 'Keep out of reach of children' (or words to that effect).
2233	FOLIC ACID	A	When for internal use, the maximum recommended daily dose must not provide more than 500 micrograms of folic acid.
			When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.
2234	FOOD ORANGE 6	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2235	FOOD ORANGE 7	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.

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2236	FOOD RED 13	Е	Permitted for use only as a colour for topical use.
2237	FORMALDEHYDE/MELAMINE/T OSYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application.
			The concentration in the medicine must be no more than 10%.
2238	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%.
2239	FORSYTHIA SUSPENSA	A, H	
2240	FORTIFIED WINE	Е	Ethanol is a mandatory component of fortified wine.
2241	FRACTIONATED COCONUT OIL	E	
2242	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

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			monograph of the British Pharmacopoeia, as in force or existing from time to time.
2243	FRAGARIA CHILOENSIS	A, E, H	
2244	FRAGARIA VESCA	A, E, H	
2245	FRAGARIA VIRGINIANA	A, E, H	
2246	FRAGARIA X ANANASSA	A, E, H	
2247	FRANGULA BARK DRY	A, H	Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark dry.  When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:  - (CHILD3) 'Use in children under 12 years is not recommended';  - (LAX2) 'Prolonged use may cause serious bowel problems'; and  - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are 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

- (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'.

FRANGULA BARK POWDER

A, H

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

When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:

- (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]'.

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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'.

2249 FRANGULA PURSHIANA

A, H

When for oral use,

hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of Frangula purshiana.

When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:

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

- (LAX2) 'Prolonged use may cause serious bowel problems'; and
- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].

When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:

- (LAX1) 'Drink plenty of water' [or words to that effect].

When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and
- (LAX4) 'This product may have laxative effect'.

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the 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'.

2250 FRAXINUS AMERICANA

A, H

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

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2251	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A, H	
2252	FRAXINUS EXCELSIOR	A, H	
2253	FRAXINUS ORNUS	A, H	
2254	FRITILLARIA CIRRHOSA	A, H	
2255	FRITILLARIA THUNBERGII	A, H	
2256	FRITILLARIA VERTICILLATA	A, H	
2257	FRUCTOOLIGOSACCHARIDES	A, E	
2258	FRUCTOSE	A, E, H	
2259	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.
2260	FULLY HYDROGENATED RAPESEED OIL	Е	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%.
2261	FUMARIA OFFICINALIS	A, E, H	
2262	FUMARIC ACID	Е, Н	Only for use as an active homoeopathic or excipient ingredient.

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

			volume 3
2263	FUMITORY HERB DRY	A, H	
2264	FUMITORY HERB POWDER	A, H	
2265	FURAMINTON	Е	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%.
2266	FURFURAL	Е	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%.
2267	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%.
2268	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%.

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

2269	FURFURYL MERCAPTAN	Е	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%.
2270	FUSEL OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2271	GALACTOOLIGOSACCHARIDES	A	Lactose and glucose are mandatory components of galactooligosaccharides.
			The route of administration for medicines that contain galactooligosaccharides must be limited to oral.
			The maximum recommended daily dose of the medicine must not provide more than:
			(a) 8 g of galactooligosaccharides to individuals aged 0 to 3 years (inclusive); and
			(b) 16.2 g of galactooligosaccharides to individuals aged 4 years and older
			The following warning statement (or words to the same effect) is required on the medicine label:
			(GOS) 'Not to be taken on the same day with other products containing galactooligosaccharides.'
2272	GALBANUM OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2273	GALBANUM RESIN	Е	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%.
2274	GALBANUM RESINOID	Е	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%.
2275	GALEGA OFFICINALIS	A, H	
2276	GALEOPSIS SEGETUM	A, H	
2277	GALIUM APARINE	A, H	
2278	GALIUM ODORATUM	A, H	When used as an active ingredient coumarin is a mandatory component of Galium odoratum and the concentration of coumarin in the medicine must be no more than 0.001%.
2279	GALIUM PALUSTRE	A, H	

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

2280	GALIUM VERUM	A, H	
2281	GALL STONE	Н	Only for use as an active homoeopathic ingredient.
2282	GALPHIMIA GLAUCA	A, H	
2283	GAMMA-4-DIMETHYL-3- CYCLOHEXENE-1-PROPANOL	Е	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%.
2284	GAMMA-BUTYROLACTONE	Е	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%.
2285	GAMMA-CYCLODEXTRIN	Е	
2286	GAMMA-DECALACTONE	E	Permitted for use only:  (a) in topical medicines for derma application; and
			<ul><li>(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</li></ul>
			When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
2287	GAMMA-DODECALACTONE	Е	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

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

			Volume 3
			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2288	GAMMA-HEPTALACTONE	Е	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%.
2289	GAMMA-HEXALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2290	GAMMA-IONONE	Е	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%.
2291	GAMMA-LINOLEIC ACID	Е	Only for use in topical medicines for dermal application.

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

2292	GAMMA-LINOLENIC ACID	E	
2293	GAMMA-N-METHYL IONONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2294	GAMMA-NONALACTONE	Е	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%.
2295	GAMMA-OCTALACTONE	Е	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%.
2296	GAMMA-TERPINENE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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

			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%.
2297	GAMMA-TOCOPHEROL	E	
2298	GAMMA-UNDECALACTONE	Е	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%.
2299	GAMMA-VALEROLACTONE	Е	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%.
2300	GANODERMA LUCIDUM	A, E, H	
2301	GARCINIA GUMMI-GUTTA	A	The requirements specified in paragraphs (a) to (c) below applies to a medicine that contains the ingredient that is:
			- listed in the Register before 1 March 2025; and
			- released for supply before 1 March 2026:
			(a) only for use in oral medicines.
			(b) must be obtained from the rind of the fruit only.

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(c) must not contain any directions for use for children or pregnant or lactating women.

The requirements specified in paragraphs (d) to (g) below apply to a medicine that contains the ingredient that is:

- listed in the Register on or after 1 March 2025; or
- released for supply on or after 1 March 2026:
- (d) the route of administration for medicines that contain Garcinia gummi-gutta must be limited to oral.
- (e) the plant part must be limited to fruit peel.
- (f) the following warning statement is required on the medicine label:
- (GARCLIV1) 'In very rare cases, Garcinia gummi-gutta 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.'
- (g) medicines containing Garcinia gummi-gutta must not be directed for use in children, or in pregnant or lactating women.

2302 GARCINIA QUAESITA

A, H

The requirements specified below apply to a medicine that contains the ingredient that is:

- listed in the Register on or after 1 March 2025; or
- released for supply on or after 1 March 2026.

When for oral use, the following warning statement is required on the medicine label:

- (GARCLIV2) 'In very rare cases, Garcinia quaesita may harm

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

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			Volume 3
			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.'
			Medicines containing Garcinia quaesita must not be directed for use in children, or in pregnant or lactating women.
2303	GARDEN BEAN	E	
2304	GARDENIA JASMINOIDES	A, E	
2305	GARDENIA TAHITENSIS FLOWER EXTRACT	Е	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%.
2306	GARLIC BULB DRY	A, E, H	
2307	GARLIC BULB FRESH	A, H	
2308	GARLIC BULB POWDER	A, E, H	
2309	GARLIC CLOVE POWDER	A, H	
2310	GARLIC OIL	A, E, H	
2311	GASTRODIA ELATA	A, H	
2312	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%.

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When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.

When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:

- the delivery device is engaged into the container in such a way that prevents it from being readily removed;
- direct suction through the delivery device results in delivery of no more than one dosage unit;
   and
- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

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

When for use in topical medicines for dermal application:

- i) the concentration of methyl salicylate in the medicine must not be more than 25%;
- ii) the following warning statements are required on the medicine label:
- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);
- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';
- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); and

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

			Volume
			- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);
			iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:
			- (IRRIT) 'If irritation develops, discontinue use'.
2313	GELATIN	A, E	
2314	GELIDIUM AMANSII	A, H	Iodine is a mandatory component of Gelidium amansii.
			Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.
			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2315	GELLAN GUM	Е	
2316	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%.
2317	GELSEMIUM POWDER	A, H	
2318	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%.
2319	GENET ABSOLUTE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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

			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%.
2320	GENTIAN DRY	A, H	
2321	GENTIAN POWDER	A, H	
2322	GENTIANA LUTEA	A, E, H	
2323	GENTIANA MACROPHYLLA	A, H	
2324	GENTIANA RHODANTHA	A, H	
2325	GENTIANA SCABRA	A, H	
2326	GENTIANELLA AMARELLA	A, H	
2327	GERANIAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2328	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%.
2329	GERANIOL	E	Permitted for use only:
			(a) in topical medicines for derma application; and
			(b) in oral medicines in combination with other permitted

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

			Volume
			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%.
2330	GERANIUM	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2331	GERANIUM MACULATUM	A, E, H	
2332	GERANIUM OIL	A, E, H	
2333	GERANIUM OIL SAPONIFIED	Е	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 OIL TERPENELESS	Е	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%.
2335	GERANIUM ROBERTIANUM	A, E, H	
2336	GERANIUM ROSE OIL	Е	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%.

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

2337	GERANIUM SIBIRICUM	A, E, H	
2338	GERANYL ACETATE	Е	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 ACETONE	Е	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%.
2340	GERANYL BUTYRATE	Е	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%.
2341	GERANYL CROTONATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a

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

			medicine must be no more than 1%.
2342	GERANYL ETHYL ETHER	Е	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%.
2343	GERANYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2344	GERANYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2345	GERANYL ISOVALERATE	Е	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%.

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

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2346	GERANYL NITRILE	Е	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%.
2347	GERANYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2348	GERANYL TIGLATE	Е	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%.
2349	GEUM RIVALE	A, H	
2350	GEUM URBANUM	A, H	
2351	GHATTI GUM	A, E, H	
2352	GIGARTINA MAMILLOSA	A, H	Iodine is a mandatory componen of Gigartina mamillosa.
			Only for external use when the concentration of iodine in the medicine (excluding salts

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

			voiume :
			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.
2353	GINGER DRY	A, E, H	
2354	GINGER OIL	A, E, H	
2355	GINGER OLEORESIN	Е	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%.
2356	GINGER POWDER	A, E, H	
2357	GINKGO BILOBA	A, E, H	The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - Nationa Formulary 27 (USP32-NF27), as in force or existing from time to time. This condition does not apply to powdered or dried leaf.
2358	GLACIAL ACETIC ACID	E, H	The concentration in the medicine must be no more than 1.5%.
2359	GLECHOMA HEDERACEA	A, H	
2360	GLECHOMA LONGITUBA	A, H	
2361	GLEDITSIA AUSTRALIS	A, H	
2362	GLEDITSIA SINENSIS	A, H	

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

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2363	GLEHNIA LITTORALIS	A, H	
2364	GLORIOSA SUPERBA	A, H	Colchicine is a mandatory component of Gloriosa superba 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%.
2365	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2366	GLUCONOLACTONE	Е	
2367	GLUCOSAMINE HYDROCHLORIDE	A, E	
2368	GLUCOSAMINE SULFATE	A	
2369	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:
			- '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.
2370	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	
2371	GLUCOSE	A, E, H	
2372	GLUCOSE GLUTAMATE	E	Only for use in topical medicines for dermal application.

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

2373	GLUCOSE MONOHYDRATE	A, E, H	
2374	GLUCOSYLRUTIN	Е	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%.
2375	GLUTAMIC ACID	A, E	Only for use in topical medicines for dermal application.
2376	GLUTAMIC ACID HYDROCHLORIDE	A, E, H	
2377	GLUTAMINE	A, E, H	
2378	GLUTARAL	Е	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%.
2379	GLUTATHIONE	A, E	When used as an active ingredien 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).
2380	GLUTEN-FREE WHEAT STARCH	 Н Е	

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

2381	GLYCERETH-26	Е	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%.
2382	GLYCEROL	A, E	When used as an active ingredient it is only for use in topical medicines for dermal application.
2383	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 Pharmacopeia-National Formulary, as in force or existing from time to time.
2384	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.
2385	GLYCERYL BEHENATE	Е	Behenic acid is a mandatory component of glyceryl behenate.
			When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.

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

			Volume 3
			In medicines for topical use, the concentration of glyceryl behenate must be no more than 5%.
2386	GLYCERYL CAPRYLATE	Е	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%.
2387	GLYCERYL DIISOSTEARATE	E	For use in topical medicines for dermal application.
2388	GLYCERYL DILAURATE	Е	Only for use in topical medicines for dermal application.
2389	GLYCERYL DIOLEATE	E	Only for use in topical medicines for dermal application.
2390	GLYCERYL DISTEARATE	E	Only for use in topical medicines for dermal application.
2391	GLYCERYL GLUCOSIDE	Е	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%.
2392	GLYCERYL ISOSTEARATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 5.5%.
2393	GLYCERYL LAURATE	Е	Only for use in topical medicines for dermal application.
2394	GLYCERYL LINOLEATE	Е	Only for use in topical medicines for dermal application.

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

2395	GLYCERYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2396	GLYCERYL MONO AND DICAPRYLOCAPRATE	Е	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.
2397	GLYCERYL MONOOLEATE	Е	
2398	GLYCERYL MONOSTEARATE	Е	
2399	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2400	GLYCERYL OLEATE CITRATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 4% of the formulation.
2401	GLYCERYL PALMITO- STEARATE	E	
2402	GLYCERYL POLYACRYLATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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

			The concentration in the medicine must be no more than 0.15%.
2403	GLYCERYL POLYMETHACRYLATE	E	Only for use in topical medicines for dermal application.
2404	GLYCERYL RICINOLEATE	Е	Only for use in topical medicines for dermal application.
2405	GLYCERYL ROSINATE	Е	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.
2406	GLYCERYL SORBITAN OLEOSTEARATE	E	Only for use in topical medicines for dermal application.
2407	GLYCERYL STARCH	Е	Only for use in topical medicines for dermal application.
			The concentration in the medicine must be no more than 4%.
			The residual levels of epichlorohydrin are to be kept below the level of detection.
2408	GLYCERYL STEARATE CITRATE	E	Only for use in topical medicines for dermal application.
			The concentration in the medicine must be no more than 5%.

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

2409	GLYCERYL TRIACETYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
			The concentration in the medicine must be no more than 6%.
2410	GLYCERYL TRIACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2411	GLYCERYL TRINITRATE	Н	Only for use as an active homoeopathic ingredient.
			The total concentration of glycery trinitrate in the medicine must not be more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
2412	GLYCERYL UNDECYLENATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration of glyceryl undecylenate in a medicine must be no more than 3%.
2413	GLYCINE	A, E	
2414	GLYCINE MAX	A, E, H	
2415	GLYCOGEN	Е	Only for use in topical medicines for dermal application.
2416	GLYCOL DISTEARATE	Е	Only for use in topical medicines for dermal application.
2417	GLYCOLIC ACID	E	Only for use in topical medicines for dermal application.
			Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.

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

			Volume 3
			When present as an excipient in sunscreens, the concentration in the medicine must be no more than 5%.  When used as an excipient ingredient in other medicines the concentration in the medicine
			must be no more than 20%.
			If the concentration is more than 5% but no more than 20%, the pH of the medicine must be 3.5 or greater.
2418	GLYCYRRHIZA GLABRA	A, E, H	
2419	GLYCYRRHIZA SPECIES	Е	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%.
2420	GLYCYRRHIZA URALENSIS	A, E, H	
2421	GLYCYRRHIZINIC ACID	Е	
2422	GNAPHALIUM AFFINE	A, H	
2423	GNAPHALIUM POLYCEPHALUM	A, H	
2424	GNAPHALIUM ULIGINOSUM	A, H	
2425	GOAT	Н	Only for use as an active homoeopathic ingredient.
2426	GOAT MILK	Е	
2427	GOLD	E, H	Only for use as an active homoeopathic or excipient ingredient.
2428	GOLD CHLORIDE	Н	Only for use as an active homoeopathic ingredient.

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

2429	GOLDEN ROD HERB DRY	A, E, H	
2430	GOLDEN SEAL ROOT DRY	A, H	
2431	GOLDEN SEAL ROOT POWDER	A, H	
2432	GOLDEN SYRUP	E	When the route of administration of the medicine is oral or sublingual, sucrose is a mandatory component of golden syrup.
2433	GOMPHRENA GLOBOSA	A, H	
2434	GOSSYPIUM HERBACEUM	A, E, H	
2435	GRAPE	Е	
2436	GRAPE SEED OIL	Е	
2437	GRAPE WINE RED	Е	Ethanol is a mandatory component of grape wine red.
2438	GRAPE WINE SHERRY	Е	Ethanol is a mandatory component of grape wine sherry.
2439	GRAPE WINE WHITE	Е	Ethanol is a mandatory component of grape wine white.
2440	GRAPEFRUIT	Е	
2441	GRAPEFRUIT OIL	Е	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%.

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

2442	GRAPEFRUIT OIL COLDPRESSED	A, E, H	
2443	GRAPEFRUIT OIL CONCENTRATE	Е	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 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%.
2445	GRAPEFRUIT OIL TERPENES AND TERPENOIDS	Е	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%.
2446	GRAPHITE	Н	Only for use as an active homoeopathic ingredient.
2447	GRATIOLA LINIFOLIA	A, H	
2448	GREATER NETTLE HERB DRY	A, H	
2449	GREATER NETTLE HERB POWDER	A, H	
2450	GREATER NETTLE ROOT DRY	A, H	

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

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

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

2461	GROUND IVY HERB POWDER	A, H	
2462	GUAIAC WOOD OIL	Е	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%.
2463	GUAIACOL	Е	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%.
2464	GUAIACUM OFFICINALE	A, E, H	
2465	GUAIACUM RESIN	А, Е, Н	
2466	GUAIACUM SANCTUM	A, H	
2467	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%.
2468	GUAIYL ACETATE	Е	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%.

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

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2469	GUANINE	Е	Only for use as an excipient in topical medicines for dermal application.
2470	GUANOSINE	Е	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.
2471	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).
2472	GUAR GUM	A, E, H	
2473	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	Е	Only for use as an excipient in topical medicines for dermal application.
2474	GUAREA RUSBYI	A, H	
2475	GUAVA	Е	
2476	GURJUN BALSAM	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.

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

			If used in a fragrance the total fragrance concentration in a
			medicine must be no more than 1%.
2477	GYMNADENIA NIGRA	A	
2478	GYMNEMA SYLVESTRE	A, H	
2479	GYMNOCLADUS DIOICA	A, H	
2480	GYNOSTEMMA PENTAPHYLLUM	A	The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).
2481	HAHNEMANN'S SOLUBLE MERCURY	Н	Only for use as an active homoeopathic ingredient.
2482	HALIBUT-LIVER OIL	A, E	Colecalciferol and Vitamin A are mandatory components of Halibut-liver oil.
			When for internal use, the
			maximum recommended daily
			dose must be no more than 25 micrograms of Vitamin D.
			When for use in topical medicines
			the concentration of Vitamin A in the medicine must be no more than 1%.
			When for internal use, the
			maximum daily dose must be no
			more than 3000 micrograms of Retinol Equivalents.
			When preparations for internal use
			in adults contain more than 33
			micrograms of retinol equivalents
			per dosage unit in divided preparations or per gram of an
			undivided preparation, the
			medicine requires the following
			warning statements on the medicine label:
			- (VITA2) 'WARNING: If you ar
			pregnant - or considering

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

			becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use (VITA3) 'The recommended
			daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
2483	HAMAMELIS LEAF DRY	A, H	
2484	HAMAMELIS LEAF POWDER	A, H	
2485	HAMAMELIS VIRGINIANA	A, E, H	
2486	HAMAMELIS WATER	A, E, H	
2487	HANDROANTHUS HEPTAPHYLLUS	A, H	
2488	HANDROANTHUS IMPETIGINOSUS	A, E, H	
2489	HARD FAT	Е	
2490	HARD PARAFFIN	Е	
2491	HARICOT BEAN	Е	

2492

HARPAGOPHYTUM

**PROCUMBENS** 

A, E, H

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

			volume 3
2493	HARUNGANA MADAGASCARIENSIS	A, H	
2494	HAZEL NUT	Е	
2495	HAZEL NUT OIL	Е	
2496	HEAVY KAOLIN	Е	
2497	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 magnesium from inorganic magnesium salts; or
			(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;
			the following warning statement is required on the medicine label:
			- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).
			When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
2498	HECTORITE	Е	Only for use in topical medicines for dermal application.

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

2499	HEDEOMA PULEGIOIDES	A	
2500	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%.
2501	HEDTA	Е	Only for use as an excipient in topical medicines for dermal application.
2502	HEKLA LAVA	Н	Only for use as an active homoeopathic ingredient.
2503	HELESTRALIS	Е	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%.
2504	HELIANTHEMUM NUMMULARIUM	A, H	
2505	HELIANTHUS ANNUUS	A, E, H	
2506	HELIANTHUS TUBEROSUS	A, H	
2507	HELICHRYSUM ANGUSTIFOLIUM	A, E, H	
2508	HELICHRYSUM ARENARIUM	A, H	
2509	HELIOTROPYL ACETATE	Е	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%.

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

			Volume
2510	HELLEBORUS NIGER	А, Н	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2511	HELLEBORUS VIRIDIS	А, Н	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2512	HELONIAS RHIZOME DRY	A, H	
2513	HELONIAS RHIZOME POWDER	A, H	
2514	HEMIDESMUS INDICUS	A, E, H	
2515	HEMP SEED OIL	A, E	Cannabidiol and tetrahydrocannabinols are mandatory components of hemp seed oil.
			The total concentration of cannabidiol in hemp seed oil mus 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 must not provide more than 36 g of hemp seed oil.
			The following warning statement (or words to that effect) are required on the medicine label:
			- 'Not for use in children under 2 years of age'; and
			- 'Not to be taken on the same da with other products containing hemp seed oil, including food sources'.

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

2516	HEPTANAL	Е	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%.
2517	HEPTANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2518	HEPTANOIC ACID	Е	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%.
2519	HEPTENAL	Е	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 ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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

			Volume
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2521	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%.
2522	HEPTYL UNDECYLENATE	Е	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%.
2523	HERACLEUM HEMSLEYANUM	A, H	
2524	HERNIARIA GLABRA	A, H	
2525	HESPERIDIN	A, E	
2526	HESPEROCYPARIS MACROCARPA	A, H	
2527	HESPEROYUCCA WHIPPLEI	A, H	
2528	HEX-3-ENYL ACETATE	Е	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	HEXAHYDRO-4,7- METHANOINDEN-6-YL PIVALATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.

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

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2530	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%.
2531	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%.
2532	HEXANE	Е	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.
2533	HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a

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

			Volume 3
			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%.
2534	HEXANOIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2535	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 %.
2536	HEXENAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2537	HEXYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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

2538	HEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2539	HEXYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2540	HEXYL CAPROATE	Е	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%.
2541	HEXYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2542	HEXYL ISOBUTYRATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.

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

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2543	HEXYL ISOVALERATE	Е	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%.
2544	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2545	HEXYL NICOTINATE	Е	
2546	HEXYL PROPIONATE	Е	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%.
2547	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%.
2548	HEXYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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

2549	HEXYLDECANOL	Е	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%.
2550	HEXYLENE GLYCOL	Е	Only for use as an excipient in topical medicines for dermal application.
2551	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).
2552	HIBISCUS ESCULENTUS	A, H	
2553	HIBISCUS MUTABILIS	A, H	
2554	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%.

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

			volume 3
2555	HIBISCUS SABDARIFFA	A, E, H	
2556	HIERACIUM PILOSELLA	A, H	
2557	HIGH AMYLOSE MAIZE STARCH	A, E, H	
2558	HIGH CHROMIUM YEAST	A, E	Chromium is a mandatory component of high chromium yeast.
			The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic chromium sources.
			High chromium yeast is considered to be an organic form of chromium.
2559	HIGH FRUCTOSE MAIZE SYRUP	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2560	HIGH MOLYBDENUM YEAST	A, E	Molybdenum is a mandatory component of high molybdenum yeast.
			The maximum daily dose of molybdenum from high molybdenum yeast must be no more than 62.5 micrograms.
2561	HIGH SELENIUM YEAST	A	When for oral or sublingual use, selenium is a mandatory component of high selenium yeast
			Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.
			When for oral use, the medicine requires the following warning statement on the medicine label:

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

			- (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.'
2562	HIMATANTHUS LANCIFOLIUS	A, E, H	
2563	HIPPOPHAE RHAMNOIDES	A, E, H	
2564	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%.
2565	HISTAMINE DIHYDROCHLORIDE	Н	Only for use as an active homoeopathic ingredient.
2566	HISTIDINE	A	
2567	HISTIDINE HYDROCHLORIDE	A, E, H	
2568	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%.
2569	HO WOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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

			v olume 3
			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%.
2570	HOLCUS LANATUS	A, H	
2571	HOLY THISTLE HERB DRY	A, H	
2572	HOLY THISTLE HERB POWDER	A, H	
2573	HOMALOMENA OCCULTA	A, H	
2574	HOMOSALATE	A, E	For use as an active ingredient only in sunscreens for dermal application.
			For use as an excipient only in topical medicines for dermal application.
			Not to be included in medicines intended for use in the eye.
			The concentration in the medicine must not be more than 15%.
			When used in primary sunscreen products, the following warning statements are required on the label:
			<ul> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> </ul>
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2575	HONEY	A, E	When the route of administration is oral, the following warning statement is required on the medicine label:

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			- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).
2576	HONEY BEE	Н	Only for use as an active homoeopathic ingredient.
2577	HONEY EXTRACT	Е	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%.
2578	HONEY POWDER	Е	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%.
2579	HOP STROBILE DRY	A, H	
2580	HOP STROBILE POWDER	A, H	
2581	HOPS OIL	A, E, H	
2582	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.
2583	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.
2584	HOREHOUND EXTRACT	Е	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%.
2585	HOTTONIA PALUSTRIS	A, H	
2586	HOUTTUYNIA CORDATA	A, H	
2587	HOVENIA DULCIS	A, H	
2588	HUMULUS LUPULUS	A, E, H	
2589	HYALURONIC ACID	Е	Only for use as an excipient in topical medicines for dermal application.
2590	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.
2591	HYDRANGEA ARBORESCENS	А, Н	
2592	HYDRANGEA PANICULATA	A, H	
2593	HYDRASTIS CANADENSIS	A, E, H	
2594	HYDRATED SILICA	Е	Only for use when the route of administration is other than inhalation.
2595	HYDROCHLORIC ACID	Е	The concentration of the medicine must be no more than 0.5%.
2596	HYDROCOTYLE UMBELLATA	A, H	
2597	HYDROGEN CYANIDE	Н	Only for use as an active homoeopathic ingredient.
2598	HYDROGEN PEROXIDE	A, E	When used as the active ingredient, it is only for use in

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			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.
2599	HYDROGENATED BUTYLENE/ETHYLENE/STYREN	Е	Only for use in topical medicines for dermal application.
	E COPOLYMER		The combined concentration of hydrogenated butylene/ethylene/stryene copolymer and hydrogenated ethylene/propylene/styrene copolymer in the medicine must be no more than 9%.
2600	HYDROGENATED C6-14 OLEFIN POLYMERS	Е	Only permitted for use in solid or semi-solid medicines for dermal application or in topical medicines for dermal application:
			(a) containing 25% or less of hydrocarbons, liquid; or
			(b) when packed in pressurised spray packs; or
			(c) when packed in containers with a capacity of 2 millilitres or less.
			Not to be included in medicines intended for use in the eye.
			The concentration in the medicine must not be more than 7%.
2601	HYDROGENATED CASTOR OIL	E	

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			Volume 3
2602	HYDROGENATED COCO- GLYCERIDES	Е	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.
			The concentration in the medicine must be no more than 3%.
2603	HYDROGENATED COCONUT OIL	Е	
2604	HYDROGENATED COTTONSEED OIL	Е	
2605	HYDROGENATED DIMER DILINOLEYL/DIMETHYLCARBO NATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.
			The concentration in the medicine must be no more than 4% in the product.
2606	HYDROGENATED ETHYLENE/PROPYLENE/STYRE NE COPOLYMER	E	The combined concentration of hydrogenated ethylene/propylene/styrene copolymer must be no more than 9%.
2607	HYDROGENATED LANOLIN	E	
2608	HYDROGENATED LECITHIN	Е	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%.
2609	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%.

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2610	HYDROGENATED PALM GLYCERIDES CITRATE	Е	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%.
2611	HYDROGENATED PALM KERNEL OIL	Е	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 medicin must be no more than 1.2%.
2612	HYDROGENATED PALM OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intende for use in the eye.
			The concentration in the medicin must be no more than 2%.
			Polycyclic aromatic hydrocarbor must be kept below the level of detection.
2613	HYDROGENATED POLYDECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intende for use in the eye.
2614	HYDROGENATED POLYDEXTROSE	A	Only permitted for use in medicines:
			(a) limited to oral routes of administration; and
			(b) when the maximum recommended daily dose does not provide more than 15 g of hydrogenated polydextrose.
2615	HYDROGENATED POLYISOBUTENE	Е	Only for use in topical medicines for dermal application.
2616	HYDROGENATED SOYA OIL	Е	

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2617	HYDROGENATED TALLOW GLYCERIDE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 3%.
2618	HYDROGENATED VEGETABLE OIL	Е	
2619	HYDROLIAC	Е	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%.
2620	HYDROLYSED ADANSONIA DIGITATA LEAF POLYSACCHARIDES	Е	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%
2621	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%.
2622	HYDROLYSED CEREAL SOLIDS	Е	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%.
2623	HYDROLYSED CHICKEN CARTILAGE EXTRACT	A	The route of administration for medicines that contain hydrolysed

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			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'.
2624	HYDROLYSED COLLAGEN	A, E	
2625	HYDROLYSED ELASTIN	Е	Only for use in topical medicines for dermal application.
2626	HYDROLYSED GELATIN	A, E	
2627	HYDROLYSED GLYCOSAMINOGLYCANS	Е	Only for use in topical medicines for dermal application.
2628	HYDROLYSED JOJOBA ESTERS	Е	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%.
2629	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%.
2630	HYDROLYSED MAIZE STARCH	E	
2631	HYDROLYSED MILK PROTEIN	Е	
2632	HYDROLYSED RICE	A, E, H	
2633	HYDROLYSED RICE PROTEIN	E	Only for use in topical medicines for dermal application and not to

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			be included in topical medicines intended for use in the eye.
			The concentration in the medicine must be no more than 0.125%.
2634	HYDROLYSED SOY PROTEIN	Е	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%.
2635	HYDROLYSED VEGETABLE PROTEIN	Е	
2636	HYDROLYSED WHEAT PROTEIN	Е	Gluten is a mandatory component of hydrolysed wheat protein.
2637	HYDROLYSED WHEAT PROTEIN/PVP CROSSPOLYMER	Е	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%.
2638	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%.
2639	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2640	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.
2641	HYDROXOCOBALAMIN	A	
2642	HYDROXYACETOPHENONE	Е	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.
			The concentration in the medicine must be no more than 1%.
2643	HYDROXYAPATITE	A, E	
2644	HYDROXYCITRATE COMPLEX	A	The requirements specified in paragraph (a) below applies to a medicine that contains the ingredient that is:
			- listed in the Register before 1 March 2025; and
			- released for supply before 1 March 2026:
			(a) hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.
			The requirements specified in paragraphs (b) to (d) below apply to a medicine that contains the ingredient that is:

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- listed in the Register on or after 1 March 2025; or
- released for supply on or after 1 March 2026:
- (b) hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.
- (c) when for oral use, the following warning statement is required on the medicine label:
- (HCLIVER) '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.'
- (d) medicines containing hydroxycitrate complex must not be directed for use in children, or in pregnant or lactating women.

### 2645 HYDROXYCITRIC ACID A

The requirements specified below apply to a medicine that contains the ingredient that is:

- listed in the Register on or after 1 March 2025; or
- released for supply on or after 1 March 2026.

When for oral use, the following warning statement is required on the medicine label:

- (HALIVER) '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.'

Medicines containing hydroxycitric acid must not be

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			directed for use in children, or in pregnant or lactating women.
2646	HYDROXYCITRONELLAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2647	HYDROXYCITRONELLAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2648	HYDROXYCITRONELLAL- METHYLANTHRANILATE	Е	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%.
2649	HYDROXYCITRONELLOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
			170.
2650	HYDROXYETHYL CETEARAMIDOPROPYLDIMONI UM CHLORIDE	Е	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 medicin must be no more than 0.1%.
2651	HYDROXYETHYL UREA	Е	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.
			The concentration must be no more than 1%.
2652	HYDROXYLATED LANOLIN	E	
2653	HYDROXYLATED MILK GLYCERIDES	Е	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.
			The concentration must be no more than 0.1%.
2654	HYDROXYLYSINE	A, E	
2655	HYDROXYMETHYLCELLULOSE	Е	
2656	HYDROXYOCTACOSANYL HYDROXYSTEARATE	Е	Only for use in topical medicines for dermal application.
2657	HYDROXYPALMITOYL SPHINGANINE	Е	Only for use in topical medicine 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 $0.1\%$ .
2658	HYDROXYPROLINE	A, E	

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2659	HYDROXYPROPYL DISTARCH	Е	Only permitted for:
	PHOSPHATE		<ul><li>use in topical medicines for dermal application; and</li><li>medicines for internal use.</li></ul>
			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.
2660	HYDROXYPROPYL STARCH	E	
2661	HYDROXYPROPYLBETADEX	Е	Only for use in topical medicines for dermal application.
2662	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%.
2663	HYETELLOSE	Е	
2664	HYLOCEREUS LEMAIREI	Е	Permitted for use only as a colour for oral and topical use.
2665	HYLOCEREUS UNDATUS	A, H	
2666	HYMETELLOSE	Е	
2667	HYOSCYAMUS LEAF DRY	A, H	Alkaloids calculated as hyoscyamine and hyoscine are mandatory components of Hyoscamus leaf dry.

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			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 hyoscine in the medicine must not be more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2668	HYOSCYAMUS LEAF POWDER	A, H	Alkaloids calculated as hyoscyamine and hyoscine 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 hyoscine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2669	HYOSCYAMUS NIGER	А, Н	Alkaloids calculated as hyoscyamine and hyoscine are mandatory components of Hyoscyamus niger.
			The concentration of hyoscyamine in the medicine must be no more than 3 micrograms/kg or 3 micrograms/L or 0.3%.
			The concentration of hyoscine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2670	HYPERICUM ASCYRON	A, H	
2671	HYPERICUM JAPONICUM	A, H	
2672	HYPERICUM PERFORATUM	A, E, H	When used for oral ingestion, the

medicine requires the following

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			warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
2673	HYPROLOSE	E	
2674	HYPROMELLOSE	E	
2675	HYPROMELLOSE PHTHALATE	Е	
2676	HYPTIS SUAVEOLENS	A, H	
2677	HYSSOPUS OFFICINALIS	A, E, H	
2678	IBERIS AMARA	A, H	
2679	ICHTHAMMOL	Н	Only for use as an active homoeopathic ingredient.
2680	ILEX AQUIFOLIUM	A, H	
2681	ILEX CHINENSIS	A, H	
2682	ILEX PARAGUARIENSIS	A, E, H	Caffeine is a mandatory component of Ilex paraguariensis.  When the medicine is packaged for supply as a divided preparatior 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 warning statements are required on the label:

- (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

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			medicines' (or words to that effect).
2683	ILEX ROTUNDA	A, H	
2684	ILEX VERTICILLATA	A, H	
2685	ILLICIUM VERUM	А, Н	When the plant preparation is oil or distillate, and the concentration of Illicium verum oil or distillate in the preparation is greater than 50%:
			(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:
			- (CHILD) 'Keep out of reach of children' (or words to that effect).
2686	IMIDUREA	Е	Only for use in topical medicines for dermal application.
2687	IMMORTELLE	Е	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%.
2688	IMMORTELLE OIL	Е	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	Е	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%.
2690	IMPATIENS BALSAMINA	A, H	
2691	IMPATIENS GLANDULIFERA	A, H	
2692	IMPERATA CYLINDRICA	A, E, H	
2693	INDIGO CARMINE	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2694	INDIGO CARMINE ALUMINIUM LAKE	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2695	INDIGOFERA TINCTORIA	A, H	
2696	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%.
2697	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.
2698	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%.

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2699	INDUSTRIAL METHYLATED SPIRIT	Е	
2700	INOSITOL	A, E	
2701	INULA BRITANNICA	A, H	
2702	INULA HELENIUM	A, E, H	
2703	INULA RACEMOSA	A, H	
2704	INULIN	A, E	
2705	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%.
2706	INVERT SUGAR	Е	
2707	INVERT SYRUP	E	When the route of administration is oral or sublingual, glucose is a mandatory component of Invert syrup.
2708	IODINE	Н	Only for use as an active homoeopathic 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.
2709	IODOPROPYNYL BUTYLCARBAMATE	Е	For use as an excipient ingredient in topical medicines only.

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			The concentration in aqueous medicines must be no more than 10%.
2710	IONONE	E	Permitted for use only:
			(a) in topical medicines for derma 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%.
2711	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%.
2712	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%.
2713	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%.
2714	IPECACUANHA PREPARED	A, H	Emetine is a mandatory component of Ipecacuanha Prepared.
			The concentration of emetine in the medicine must be no more than 0.2%.

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2715	IPECACUANHA ROOT LIQUID EXTRACT	А, Н	Emetine is a mandatory component of Ipecacuanha root liquid extract.
			The concentration of emetine in the medicine must be no more than 0.2%.
2716	IPOMOEA BATATAS	A, H	
2717	IPOMOEA JALAPA	A, H	
2718	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.
2719	IRIS DOMESTICA	A, H	
2720	IRIS FLORENTINA	A, H	
2721	IRIS GERMANICA	A, H	
2722	IRIS PALLIDA	A, H	
2723	IRIS TENAX	Н	
2724	IRIS VERSICOLOR	A, H	
2725	IRON	А, Н	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

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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 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.

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

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:

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

# 2726 IRON (II) BISGLYCINE SULFATE A TRIHYDRATE

Only for use in oral medicines.

Iron is a mandatory component of iron (II) bisglycine sulfate trihydrate.

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

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per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.

In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).

Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:

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

#### 2727 IRON (II) GLYCINATE

Only for use in oral medicines.

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

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

If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.

Α

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

In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).

Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:

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

#### 2728 IRON (III) GLYCINATE

Α

Only for use in oral medicines.

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

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

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

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present as an excipient at a quantity of no more than 1%).

Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.

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

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:

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

#### 2729

#### IRON AMINO ACID CHELATE

#### A, H

Only for use in oral medicines.

When used internally, iron is a mandatory component of iron amino acid chelate.

The concentration of iron in iron amino acid chelate must be no more than 25%.

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.

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In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).

Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.

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

When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:

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

#### 2730 IRON OXIDE BLACK

Permitted for use only as a colour in medicines limited to topical and oral routes of administration.

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.

When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.

Е

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

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2731	IRON OXIDE RED	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
			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.
			When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.
2732	IRON OXIDE YELLOW	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
			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.
			When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.
2733	IRON PHOSPHATE	A, E, H	When used internally, iron is a mandatory component of iron phosphate and must be declared.
			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

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

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			Volume 3
			(excluding iron oxides when present as an excipient at a quantity of no more than 1%).  Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.
			Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.
			When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:
			- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2734	IRONE	Е	
2735	IRVINGIA GABONENSIS SEED TRIGLYCERIDES	Е	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.
			The concentration must be no more than 0.375%.
2736	ISATIS TINCTORIA	A, H	
2737	ISOAMBRETTOLIDE	Е	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

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

			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2738	ISOAMYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitte ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2739	ISOAMYL ACETATE	E	Permitted for use only in combination with other permitte 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 ALCOHOL	Е	Permitted for use only in combination with other permitte 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 BENZOATE	Е	Permitted for use only in combination with other permitte ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a

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

			Volume
			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 BUTYRATE	Е	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%.
2743	ISOAMYL CAPRYLATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2744	ISOAMYL CINNAMATE	Е	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%.

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

2745	ISOAMYL CITRONELLYL KETONE	Е	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%.
2746	ISOAMYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2747	ISOAMYL HEXANOATE	Е	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%.
2748	ISOAMYL ISOBUTYRATE	Е	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%.

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

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2749	ISOAMYL ISOVALERATE	Е	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%.
2750	ISOAMYL LAURATE	Е	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 12%.
2751	ISOAMYL METHOXYCINNAMATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must not be more than 10%.
			When used in primary sunscreen products, the following warning statements are required on the label:
			<ul> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> </ul>
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2752	ISOAMYL PHENYLACETATE	Е	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

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

			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2753	ISOAMYL PHENYLETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation
			The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
2754	ISOAMYL PROPIONATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2755	ISOAMYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2756	ISOBERGAMIATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a

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

			medicine must be no more than 1%.
2757	ISOBORNEOL	Е	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%.
2758	ISOBORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2759	ISOBORNYL CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2760	ISOBUTANE	Е	Only for use in topical medicines for dermal application.
2761	ISOBUTYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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

			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%.
2762	ISOBUTYL ALCOHOL	E	The residual solvent limit for Isobutyl alcohol is 50mg per recommended daily dose.
			The concentration of isobutyl alcohol must be no more than 0.5% of the formulation.
2763	ISOBUTYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
2764	ISOBUTYL BENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
2765	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%.
2766	ISOBUTYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2767	ISOBUTYL CINNAMATE	Е	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 FORMATE	Е	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%.
2769	ISOBUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
2770	ISOBUTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2771	ISOBUTYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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

2772	ISOBUTYL PHENYLACETATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2773	ISOBUTYL PROPIONATE	Е	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%.
2774	ISOBUTYL QUINOLINE	Е	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%.
2775	ISOBUTYL SALICYLATE	Е	Only for use in topical medicines for dermal application.
2776	ISOBUTYLENE/ISOPRENE COPOLYMER	Е	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.
2777	ISOBUTYRALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2778	ISOBUTYRIC ACID	Е	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%.
2779	ISOCETYL ALCOHOL	Е	Only for use in topical medicines for dermal application.
2780	ISOCETYL LINOLEOYL STEARATE	Е	Only for use in topical medicines for dermal application.
2781	ISOCETYL STEARATE	Е	Only for use in topical medicines for dermal application.
2782	ISOCETYL STEAROYL STEARATE	Е	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%.
2783	ISOCYCLOCITRAL	Е	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%.
2784	ISODECYL ISONONANOATE	Е	Only for use in topical medicines for dermal application.

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

2785	ISODECYL NEOPENTANOATE	Е	Only for use in topical medicines for dermal application.
2786	ISODECYL OLEATE	E	Only for use in topical medicines for dermal application.
2787	ISODECYL SALICYLATE	Е	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%.
2788	ISODODECANE	Е	Only for use in topical medicine for dermal application.
2789	ISOEICOSANE	Е	Only for use in topical medicine 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%.
2790	ISOEUGENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
			When the medicine is for derma use, the total concentration of isoeugenol in the medicine must not be more than 0.02%.
2791	ISOEUGENYL ACETATE	Е	Permitted for use only in combination with other permitte

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

			Volume
			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%.
2792	ISOEUGENYL BENZYL ETHER	Е	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%.
2793	ISOHEXADECANE	Е	Only for use in topical medicines for dermal application.
2794	ISOJASMONE	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation.
			The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
			The total fragrance proprietary excipient formulation in a medicine must not be more 1%.
2795	ISOLEUCINE	A, E	
2796	ISOMALT	Е	
2797	ISOMENTHONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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

			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%.
2798	ISOMETHYLIONONE	Е	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%.
2799	ISONONYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2800	ISONONYL ISONONANOATE	Е	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.
			The concentration must be no more than 15%.
2801	ISOPENTANE	E	For dental use only.
			The concentration must be no more than 2%.
2802	ISOPENTANOIC ACID	Е	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

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

			Volume
			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2803	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%.
2804	ISOPHYTOL	Е	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%.
2805	ISOPROPYL 2- METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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

2806	ISOPROPYL 4- HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
2807	ISOPROPYL ACETATE	E	Only for use in topical medicines for dermal application.
2808	ISOPROPYL ALCOHOL	Е	
2809	ISOPROPYL CAPROATE	Е	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 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%.
2811	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
2812	ISOPROPYL LANOLATE	Е	Only for use in topical medicines for dermal application.
2813	ISOPROPYL LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.
			The concentration must be no more than 5.6%.
2814	ISOPROPYL MYRISTATE	E	
2815	ISOPROPYL PALMITATE	Е	Only for use in topical medicines for dermal application.

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

			Volume 3
2816	ISOPROPYL PPG-2 ISODECETH-7 CARBOXYLATE	Е	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%.
2817	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2818	ISOPROPYL TITANIUM TRIISOSTEARATE	Е	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%.
2819	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%.
2820	ISOPULEGOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2821	ISORALDEINE 70	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a

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

			medicine must be no more than 1%.
2822	ISOSTEARIC ACID	Е	Only for use in topical medicines for dermal application.
2823	ISOSTEAROYL HYDROLYSED COLLAGEN	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration must be no more than 0.3%.
2824	ISOSTEARYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2825	ISOSTEARYL NEOPENTANOATE	Е	Only for use in topical medicines for dermal application.
2826	ISOSTEARYL PALMITATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration must be no more than 2%.
2827	ISOTRIDECYL ALCOHOL	Е	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%.
2828	ISOVALERALDEHYDE	Е	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%.

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

			Volume 3
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2829	ISOVALERIC ACID	Е	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%.
2830	ISPAGHULA HUSK DRY	А, Н	When a dose for children is stated, the following warning statement is required on the label:
			<ul> <li>(PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</li> </ul>
2831	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).
2832	IVA AXILLARIS	A, H	
2833	JAMAICA DOGWOOD BARK DRY	A, H	
2834	JAMAICA DOGWOOD BARK POWDER	A, H	
2835	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

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

			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2836	JASMINE LACTONE	Е	Only for use in topical medicines for dermal application.
2837	JASMINE OIL	Е	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%.
2838	JASMINUM GRANDIFLORUM	Е	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%.
2839	JASMINUM OFFICINALE	A, E, H	
2840	JASSOLIA	Е	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%.
2841	JATEORHIZA PALMATA	A, H	
2842	JATROPHA CURCAS	Н	Only for use as an active homoeopathic ingredient.
2843	JERUSALEM ARTICHOKE	Е	

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

Vol	ume	3
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			volume 3
2844	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%.
2845	JUGLANS CINEREA	A, E, H	
2846	JUGLANS NIGRA	A, E, H	
2847	JUGLANS REGIA	A, H	
2848	JUNCUS EFFUSUS	A, H	
2849	JUNIPER BERRY OIL	A, E, H	
2850	JUNIPER BERRY OIL TERPENELESS	Е	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%.
2851	JUNIPERUS CALIFORNICA	A, H	
2852	JUNIPERUS COMMUNIS	A, E, H	
2853	JUNIPERUS DEPPEANA	Е	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%.
2854	JUNIPERUS OXYCEDRUS	A, H	
2855	JUNIPERUS VIRGINIANA	A, E, H	
2856	JUSTICIA ADHATODA	A, H	