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

Note: See sections 5 and 6.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2175	FABIANA IMBRICATA	A, H	
2176	FAGOPYRUM ESCULENTUM	A, H	
2177	FAGUS GRANDIFOLIA	A, H	
2178	FAGUS SYLVATICA	A, H	
2179	FARNESOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2180	FARNESYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
2181	FAST GREEN FCF	E	Permitted for use only as a colour in medicines limited to topical and oral routes of

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			administration.
2182	FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2183	FENCHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2184	FENCHYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2185	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'

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.'
2186	FENNEL LEAF	E	
2187	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.'
2188	FENNEL SWEET SEED DRY	A, E, H	When used in oral medicines, the following warning statements are required on the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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	FENUGREEK	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2190	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%.
2191	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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2192	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2193	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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2194	FERRIC GLYCEROPHOSPHATE	A, E, H	When for internal use, iron is a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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 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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			effect).
2195	FERRIC OXIDE	E	
2196	FERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2197	FERRIC PYROPHOSPHATE	A, H	When for internal use, iron is a mandatory component of ferric pyrophosphate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2198	FERROSOFERRIC OXIDE	E	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.
2199	FERROSOFERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2200	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 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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			present as an excipient at a quantity of no more than1%). 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).
2201	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 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2202	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 dose of no more than 24 mg of iron. If the divided dosage form

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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 IODIDE	H	Only for use as an active homoeopathic ingredient.

Permissible ingredients and requirements

Column 1	Column 2	Column 3	Column 4
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2204	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 than1%). 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

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			treatment of iron deficiency conditions' (or words to that effect).
2205	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2206	FERROUS PICRATE	H	Only for use as an active homoeopathic ingredient.
2207	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.

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2208	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2209	FERULA ASSA-FOETIDA	A, E, H	
2210	FERULA FOETIDA	A, E, H	
2211	FERULA GALBANIFLUA	A, E, H	
2212	FERULA RUBRICAULIS	A, E, H	
2213	FERULA SUMBUL	A, H	
2214	FERULIC ACID	E	Only for use in topical medicines for dermal application.
2215	FESTUCA ELATIOR	A, H	
2216	FEVERFEW HERB DRY	A, H	
2217	FEVERFEW HERB POWDER	A, H	
2218	FICUS CARICA	A, E, H	
2219	FICUS PUMILA	A, H	
2220	FIG	E	
2221	FIG DRY	A, H	
2222	FILIPENDULA ULMARIA	A, H	Methyl salicylate is a mandatory component of Filipendula ulmaria. Not to be included in medicines for use in the eye or

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25%; ii) the following warning statements are required on the medicine label:

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
2223	FIR BALSAM ABSOLUTE	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%.
2224	FIR NEEDLE OIL CANADIAN	A, E	
2225	FIR NEEDLE OIL SIBERIAN	A, E	
2226	FIRMIANA SIMPLEX	A, E, H	
2227	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2228	FLEMINGIA MACROPHYLLA	A, H	
2229	FLOUVE OIL	E	Permitted for use only in combination with other permitted ingredients as a

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2230	FLUORESCEIN SODIUM	E	
2231	FOENICULUM VULGARE	A, E, H	When used in oral medicines, the following warning statements are required on the label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.' When the plant preparation is oil or distillate, methyl chavicol is a mandatory component and the maximum daily dose must provide no more than 150 mg of the plant preparation. When the plant preparation is oil or distillate and the concentration of methyl 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).

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2232	FOLIC ACID	A	When for internal use, the maximum recommended daily dose must be no more than 500 micrograms of folic acid. When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose. When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects: a) the maximum daily dose must provide 400 – 500 micrograms of folic acid; and b) the following statement must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'.
2233	FOOD ORANGE 6	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2234	FOOD ORANGE 7	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2235	FOOD RED 13	E	Permitted for use only as a

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			colour for topical use.
2236	FORMALDEHYDE/MELAMINE/TOSYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
2237	FORMIC ACID	H	Only for use as an active homoeopathic ingredient.
2238	FORSYTHIA SUSPENSA	A, H	
2239	FORTIFIED WINE	E	Ethanol is a mandatory component of fortified wine. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'.
2240	FRACTIONATED COCONUT OIL	E	
2241	FRACTIONATED PALM KERNEL OIL	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2242	FRAGARIA CHILOENSIS	A, E, H	
2243	FRAGARIA VESCA	A, E, H	
2244	FRAGARIA VIRGINIANA	A, E, H	
2245	FRAGARIA X ANANASSA	A, E, H	
2246	FRANGULA BARK DRY	A, H	Glucofrangulins calculated as

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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 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'.

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
2247	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
2248	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,

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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	FRAXINUS AMERICANA	A, H	
2250	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A, H	
2251	FRAXINUS EXCELSIOR	A, H	
2252	FRAXINUS ORNUS	A, H	
2253	FRITILLARIA CIRRHOSA	A, H	
2254	FRITILLARIA THUNBERGII	A, H	
2255	FRITILLARIA VERTICILLATA	A, H	
2256	FRUCTOOLIGOSACCHARIDES	A, E	
2257	FRUCTOSE	A, E, H	
2258	FUCUS VESICULOSUS	A, E, H	Iodine is a mandatory component of Fucus vesiculosus. Only for external use when the concentration of available iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2259	FUMARIA OFFICINALIS	A, E, H	

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2260	FUMARIC ACID	E, H	Only for use as an active homoeopathic or excipient ingredient.
2261	FUMITORY HERB DRY	A, H	
2262	FUMITORY HERB POWDER	A, H	
2263	FURAMINTON	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2264	FURFURAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2265	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%.
2266	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
2267	FURFURYL MERCAPTAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2268	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%.
2269	GALBANUM OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2270	GALBANUM PHENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2271	GALBANUM RESIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2272	GALBANUM RESINOID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2273	GALEGA OFFICINALIS	A, H	
2274	GALEOPSIS SEGETUM	A, H	
2275	GALIUM APARINE	A, H	
2276	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%.
2277	GALIUM PALUSTRE	A, H	
2278	GALIUM VERUM	A, H	
2279	GALL STONE	H	Only for use as an active homoeopathic ingredient.
2280	GALPHIMIA GLAUCA	A, H	
2281	GAMMA-4-DIMETHYL-3-CYCLOHEXENE-1-PROPANOL	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2282	GAMMA-BUTYROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2283	GAMMA-CYCLODEXTRIN	E	
2284	GAMMA-DECALACTONE	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
2285	GAMMA-DODECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total 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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2286	GAMMA-HEPTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2287	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%.
2288	GAMMA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2289	GAMMA-LINOLEIC ACID	E	Only for use in topical medicines for dermal application.
2290	GAMMA-LINOLENIC ACID	E	
2291	GAMMA-N-METHYL IONONE	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2292	GAMMA-NONALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2293	GAMMA-OCTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2294	GAMMA-TERPINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2295	GAMMA-TOCOPHEROL	E	
2296	GAMMA-UNDECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2297	GAMMA-VALEROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2298	GANODERMA LUCIDUM	A, E, H	
2299	GARCINIA GUMMI-GUTTA	A	Only for use in oral medicines. Must be obtained from the rind of the fruit only. Must not contain any directions for use for children or pregnant or lactating women.
2300	GARCINIA QUAESITA	A, H	
2301	GARDEN BEAN	E	
2302	GARDENIA JASMINOIDES	A, E	
2303	GARDENIA TAHITENSIS FLOWER EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%
2304	GARLIC BULB DRY	A, E, H	
2305	GARLIC BULB FRESH	A, H	
2306	GARLIC BULB POWDER	A, E, H	
2307	GARLIC CLOVE POWDER	A, H	
2308	GARLIC OIL	A, E, H	
2309	GASTRODIA ELATA	A, H	
2310	GAULTHERIA PROCUMBENS	A, E, H	Methyl salicylate is a mandatory component of Gaultheria procumbens. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application i) the concentration of methyl salicylate in the medicine must not be more than 25%; ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2311	GELATIN	A, E	
2312	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.
2313	GELLAN GUM	E	
2314	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%.
2315	GELSEMIUM POWDER	A, H	
2316	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%.
2317	GENET ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2318	GENTIAN DRY	A, H	
2319	GENTIAN POWDER	A, H	

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2320	GENTIANA LUTEA	A, E, H	
2321	GENTIANA MACROPHYLLA	A, H	
2322	GENTIANA RHODANTHA	A, H	
2323	GENTIANA SCABRA	A, H	
2324	GENTIANELLA AMARELLA	A, H	
2325	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%.
2326	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%.
2327	GERANIOL	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
2328	GERANIUM	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2329	GERANIUM MACULATUM	A, E, H	
2330	GERANIUM OIL	A, E, H	
2331	GERANIUM OIL SAPONIFIED	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2332	GERANIUM OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2333	GERANIUM ROBERTIANUM	A, E, H	
2334	GERANIUM ROSE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2335	GERANIUM SIBIRICUM	A, E, H	
2336	GERANYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2337	GERANYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2338	GERANYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2339	GERANYL CROTONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2340	GERANYL ETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2341	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%.
2342	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%.
2343	GERANYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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 NITRILE	E	Permitted for use only in

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2345	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%.
2346	GERANYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2347	GEUM RIVALE	A, H	
2348	GEUM URBANUM	A, H	
2349	GHATTI GUM	A, E, H	
2350	GIGARTINA MAMILLOSA	A, H	Iodine is a mandatory component of Gigartina mamillosa. 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			300 micrograms of iodine per maximum recommended daily dose.
2351	GINGER DRY	A, E, H	
2352	GINGER OIL	A, E, H	
2353	GINGER OLEORESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
2354	GINGER POWDER	A, E, H	
2355	GINKGO BILOBA	A, E, H	The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27), as in force or existing from time to time. This condition does not apply to powdered or dried leaf.
2356	GLACIAL ACETIC ACID	E, H	The concentration in the medicine must be no more than 1.5%.
2357	GLECHOMA HEDERACEA	A, H	
2358	GLECHOMA LONGITUBA	A, H	
2359	GLEDITSIA AUSTRALIS	A, H	
2360	GLEDITSIA SINENSIS	A, H	
2361	GLEHNIA LITTORALIS	A, H	
2362	GLORIOSA SUPERBA	A, H	Colchicine is a mandatory

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2363	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2364	GLUCONOLACTONE	E	
2365	GLUCOSAMINE HYDROCHLORIDE	A, E	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2366	GLUCOSAMINE SULFATE	A	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2367	GLUCOSAMINE SULFATE POTASSIUM CHLORIDE	A	Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride. When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'. When for oral use, the medicine requires the following warning statement on the medicine label: - (POTAS) ‘Contains [amount of potassium in milligrams] mg

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			of potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'
2368	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2369	GLUCOSE	A, E, H	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
2370	GLUCOSE GLUTAMATE	E	Only for use in topical medicines for dermal application.

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2371	GLUCOSE MONOHYDRATE	A, E, H	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose monohydrate, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
2372	GLUCOSYLRUTIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
2373	GLUTAMIC ACID	A, E	Only for use in topical medicines for dermal application.
2374	GLUTAMIC ACID HYDROCHLORIDE	A, E, H	
2375	GLUTAMINE	A, E, H	
2376	GLUTARAL	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2377	GLUTATHIONE	A, E	When used as an active ingredient, glutathione can only be used in medicines with an oral route of administration and must be indicated for use in adults only and not in pregnant or lactating women. The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (ADULT) 'Adults only' (or words to that effect).
2378	GLUTEN-FREE WHEAT STARCH	E	
2379	GLYCERETH-26	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
2380	GLYCEROL	A, E	When used as an active ingredient, it is only for use in topical medicines for dermal application.
2381	GLYCEROL ESTER OF PARTIALLY HYDROGENATED GUM ROSIN	E	Only for use when the dosage form is 'chewing gum'.

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
2382	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.
2383	GLYCERYL BEHENATE	E	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. In medicines for topical use, the concentration of glyceryl behenate must be no more than 5%.
2384	GLYCERYL CAPRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 1%.
2385	GLYCERYL DIISOSTEARATE	E	For use in topical medicines for dermal application.
2386	GLYCERYL DILAURATE	E	Only for use in topical medicines for dermal application.
2387	GLYCERYL DIOLEATE	E	Only for use in topical medicines for dermal application.
2388	GLYCERYL DISTEARATE	E	Only for use in topical medicines for dermal application.
2389	GLYCERYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2390	GLYCERYL ISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5.5%.
2391	GLYCERYL LAURATE	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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2392	GLYCERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2393	GLYCERYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2394	GLYCERYL MONOOLEATE	E	
2395	GLYCERYL MONOSTEARATE	E	
2396	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2397	GLYCERYL OLEATE CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4% of the formulation.
2398	GLYCERYL PALMITO-STEARATE	E	
2399	GLYCERYL POLYACRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.
2400	GLYCERYL POLYMETHACRYLATE	E	Only for use in topical medicines for dermal application.
2401	GLYCERYL RICINOLEATE	E	Only for use in topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
2402	GLYCERYL ROSINATE	E	Only for use when the dosage form is 'chewing gum'. Must comply with: a) the Glycerol Ester of Gum Rosin monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia National Formulary, as in force or existing from time to time.
2403	GLYCERYL SORBITAN OLEOSTEARATE	E	Only for use in topical medicines for dermal application.
2404	GLYCERYL STARCH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 4%. The residual levels of epichlorohydrin are to be kept below the level of detection.
2405	GLYCERYL STEARATE CITRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
2406	GLYCERYL TRIACETYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application. The concentration in the medicine must be no more than 6%.
2407	GLYCERYL TRIACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2408	GLYCERYL TRINITRATE	H	Only for use as an active homoeopathic ingredient.
2409	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%.
2410	GLYCINE	A, E	
2411	GLYCINE MAX	A, E, H	
2412	GLYCOGEN	E	Only for use in topical medicines for dermal application.
2413	GLYCOL DISTEARATE	E	Only for use in topical medicines for dermal application.
2414	GLYCOLIC ACID	E	Only for use in topical medicines for dermal application. Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose. When present as an excipient

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
2415	GLYCYRRHIZA GLABRA	A, E, H	
2416	GLYCYRRHIZA SPECIES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2417	GLYCYRRHIZA URALENSIS	A, E, H	
2418	GLYCYRRHIZINIC ACID	E	
2419	GNAPHALIUM AFFINE	A, H	
2420	GNAPHALIUM POLYCEPHALUM	A, H	
2421	GNAPHALIUM ULIGINOSUM	A, H	
2422	GOAT	H	Only for use as an active homoeopathic ingredient.
2423	GOAT MILK	E	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
2424	GOLD	E, H	Only for use as an active homoeopathic or excipient

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			ingredient.
2425	GOLD CHLORIDE	H	Only for use as an active homoeopathic ingredient.
2426	GOLDEN ROD HERB DRY	A, E, H	
2427	GOLDEN SEAL ROOT DRY	A, H	
2428	GOLDEN SEAL ROOT POWDER	A, H	
2429	GOLDEN SYRUP	E	Sucrose is a mandatory component of Golden syrup when the route of administration of the medicine is oral or sublingual. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
2430	GOMPHRENA GLOBOSA	A, H	
2431	GOOSEBERRY	E	
2432	GOSSYPIUM HERBACEUM	A, E, H	
2433	GRAPE	E	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2434	GRAPE SEED OIL	E	
2435	GRAPE WINE RED	E	Ethanol is a mandatory component of Grape wine red. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2436	GRAPE WINE SHERRY	E	Ethanol is a mandatory component of Grape wine sherry. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2437	GRAPE WINE WHITE	E	Ethanol is a mandatory component of Grape wine white. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2438	GRAPEFRUIT	E	
2439	GRAPEFRUIT OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2440	GRAPEFRUIT OIL COLDPRESSED	A, E, H	
2441	GRAPEFRUIT OIL CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2442	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%.
2443	GRAPEFRUIT OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2444	GRAPHITE	H	Only for use as an active homoeopathic ingredient.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2445	GRATIOLA LINIFOLIA	A, H	
2446	GREATER NETTLE HERB DRY	A, H	
2447	GREATER NETTLE HERB POWDER	A, H	
2448	GREATER NETTLE ROOT DRY	A, H	
2449	GREATER NETTLE ROOT POWDER	A, H	
2450	GREEN LIPPED MUSSEL	A	
2451	GREEN LIPPED MUSSEL DRIED	A	
2452	GREEN LIPPED MUSSEL OIL	A	
2453	GREEN S	E	Only for use as a colour in topical and oral medicines.
2454	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.'
2455	GRINDELIA CAMPORUM	A, H	
2456	GRINDELIA ROBUSTA	A, H	
2457	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%.
2458	GROUND IVY HERB DRY	A, H	
2459	GROUND IVY HERB POWDER	A, H	
2460	GUAIAC WOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2461	GUAIACOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
2462	GUAIACUM OFFICINALE	A, E, H	
2463	GUAIACUM RESIN	A, E, H	
2464	GUAIACUM SANCTUM	A, H	
2465	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%.
2466	GUAIYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2467	GUANINE	E	Only for use as an excipient in topical medicines for dermal application.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2468	GUANOSINE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 0.01% in the medicine.
2469	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).
2470	GUAR GUM	A, E, H	
2471	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	E	Only for use as an excipient in topical medicines for dermal application.
2472	GUAREA RUSBYI	A, H	
2473	GUAVA	E	
2474	GURJUN BALSAM	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more than 1%.
2475	GYMNADENIA NIGRA	A	
2476	GYMNEMA SYLVESTRE	A, H	
2477	GYMNOCLADUS DIOICA	A, H	
2478	GYNOSTEMMA PENTAPHYLLUM	A	The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).
2479	GYNURA JAPONICA	A, H	
2480	HAHNEMANN'S SOLUBLE MERCURY	H	Only for use as an active homoeopathic ingredient.
2481	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
2482	HAMAMELIS LEAF DRY	A, H	
2483	HAMAMELIS LEAF POWDER	A, H	
2484	HAMAMELIS VIRGINIANA	A, E, H	
2485	HAMAMELIS WATER	A, E, H	
2486	HANDROANTHUS HEPTAPHYLLUS	A, H	
2487	HANDROANTHUS IMPETIGINOSUS	A, E, H	
2488	HARD FAT	E	
2489	HARD PARAFFIN	E	
2490	HARICOT BEAN	E	
2491	HARPAGOPHYTUM PROCUMBENS	A, E, H	
2492	HARUNGANA MADAGASCARIENSIS	A, H	
2493	HAZEL NUT	E	
2494	HAZEL NUT OIL	E	

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2495	HEAVY KAOLIN	E	
2496	HEAVY MAGNESIUM OXIDE	A, E, H	
2497	HECTORITE	E	Only for use in topical medicines for dermal application.
2498	HEDEOMA PULEGIOIDES	A	
2499	HEDERA HELIX	A, H	Emetine is a mandatory component of Hedera helix. The concentration of emetine in the medicine must be no more than 0.2%.
2500	HEDTA	E	Only for use as an excipient in topical medicines for dermal application.
2501	HEKLA LAVA	H	Only for use as an active homoeopathic ingredient.
2502	HELESTRALIS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2503	HELIANTHEMUM NUMMULARIUM	A, H	
2504	HELIANTHUS ANNUUS	A, E, H	
2505	HELIANTHUS TUBEROSUS	A, H	
2506	HELICHRYSUM ANGUSTIFOLIUM	A, E, H	
2507	HELICHRYSUM ARENARIUM	A, H	
2508	HELIOTROPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2509	HELLEBORUS NIGER	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2510	HELLEBORUS VIRIDIS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2511	HELONIAS RHIZOME DRY	A, H	
2512	HELONIAS RHIZOME POWDER	A, H	
2513	HEMIDESMUS INDICUS	A, E, H	
2514	HEPTANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2515	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%.
2516	HEPTANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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	HEPTENAL	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	HEPTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2519	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%.
2520	HEPTYL UNDECYLENATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 25%.
2521	HERACLEUM HEMSLEYANUM	A, H	
2522	HERNIARIA GLABRA	A, H	
2523	HESPERIDIN	A, E	
2524	HESPEROCYPARIS MACROCARPA	A, H	
2525	HESPEROYUCCA WHIPPLEI	A, H	
2526	HEX-3-ENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2527	HEXAHYDRO-4,7-METHANOINDEN-6-YL PIVALATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2528	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%.
2529	HEXAN-1-OL	E	Permitted for use only in combination with other

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2530	HEXANE	E	The concentration of the medicine must be no more than 0.029%. When used for a route of administration other than topical, the residual solvent limit for Hexane is 2.9 mg per recommended daily dose.
2531	HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2532	HEXANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2533	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 %.
2534	HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2535	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%.
2536	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%.

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2537	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%.
2538	HEXYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2539	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%.
2540	HEXYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2541	HEXYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2542	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2543	HEXYL NICOTINATE	E	
2544	HEXYL PROPIONATE	E	Only for use in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
2545	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%.
2546	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%.
2547	HEXYLDECANOL	E	Only for use as an excipient in topical medicines for dermal application and not to be

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in topical medicines intended for use in the eye. The concentration of the medicine must be no more than 3%.
2548	HEXYLENE GLYCOL	E	Only for use as an excipient in topical medicines for dermal application.
2549	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).
2550	HIBISCUS ESCULENTUS	A, H	
2551	HIBISCUS MUTABILIS	A, H	
2552	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%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2553	HIBISCUS SABDARIFFA	A, E, H	
2554	HIERACIUM PILOSELLA	A, H	
2555	HIGH AMYLOSE MAIZE STARCH	A, E, H	
2556	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.
2557	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%.
2558	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.
2559	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

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine requires the following warning statement on the medicine label: - (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.'
2560	HIMATANTHUS LANCIFOLIUS	A, E, H	
2561	HIPPOPHAE RHAMNOIDES	A, E, H	
2562	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%.
2563	HISTAMINE DIHYDROCHLORIDE	H	Only for use as an active homoeopathic ingredient.
2564	HISTIDINE	A	
2565	HISTIDINE HYDROCHLORIDE	A, E, H	
2566	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%.
2567	HO WOOD OIL	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2568	HOLCUS LANATUS	A, H	
2569	HOLY THISTLE HERB DRY	A, H	
2570	HOLY THISTLE HERB POWDER	A, H	
2571	HOMALOMENA OCCULTA	A, H	
2572	HOMOSALATE	A, E	For use as an active ingredient only in sunscreens for dermal application. For use as an excipient only in topical medicines for dermal application. Not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 15%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2573	HONEY	A, E	When the route of administration is oral, the medicine requires the following warning statement

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
2574	HONEY BEE	H	Only for use as an active homoeopathic ingredient.
2575	HONEY EXTRACT	E	Not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar,

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.
2576	HONEY POWDER	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2577	HOP STROBILE DRY	A, H	
2578	HOP STROBILE POWDER	A, H	
2579	HOPS OIL	A, E, H	
2580	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.
2581	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.
2582	HOREHOUND EXTRACT	E	Permitted for use only in combination with other

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2583	HORSE RADISH	E, H	Volatile oil components (of Armoracia rusticana) is a mandatory component of Horse radish. The maximum recommended daily dose must be no more than 20 mg of volatile oil components (of Armoracia rusticana).
2584	HOTTONIA PALUSTRIS	A, H	
2585	HOUTTUYNIA CORDATA	A, H	
2586	HOVENIA DULCIS	A, H	
2587	HUMULUS LUPULUS	A, E, H	
2588	HYALURONIC ACID	E	Only for use as an excipient in topical medicines for dermal application.
2589	HYDNOCARPUS ANTHELMINTICA	A, H	When the medicine is for other than topical use and the plant part is seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry seed.
2590	HYDRANGEA ARBORESCENS	A, H	
2591	HYDRANGEA PANICULATA	A, H	
2592	HYDRASTIS CANADENSIS	A, E, H	
2593	HYDRATED SILICA	E	Only for use when the route of administration is other than inhalation.
2594	HYDROCHLORIC ACID	E	The concentration of the medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			0.5%.
2595	HYDROCOTYLE UMBELLATA	A, H	
2596	HYDROFLUORIC ACID	H	Only for use as an active homoeopathic ingredient.
2597	HYDROGEN CYANIDE	H	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 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/STYRENE COPOLYMER	E	Only for use in topical medicines for dermal application. 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	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 7%.
2601	HYDROGENATED CASTOR OIL	E	
2602	HYDROGENATED COCO-GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
2603	HYDROGENATED COCONUT OIL	E	
2604	HYDROGENATED COTTONSEED OIL	E	
2605	HYDROGENATED DIMER DILINOLEYL/DIMETHYLCARBONATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 4% in the product.
2606	HYDROGENATED ETHYLENE/PROPYLENE/STYRENE COPOLYMER	E	The combined concentration of hydrogenated ethylene/propylene/styrene copolymer must be no more than 9%.
2607	HYDROGENATED LANOLIN	E	
2608	HYDROGENATED LECITHIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2610	HYDROGENATED PALM GLYCERIDES CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.01%.
2611	HYDROGENATED PALM KERNEL OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.2%.
2612	HYDROGENATED PALM OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. Polycyclic aromatic hydrocarbons must be kept below the level of detection.
2613	HYDROGENATED POLYDECENE	E	Only for use in topical

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines for dermal application and not to be included in medicines intended for use in the eye.
2614	HYDROGENATED POLYDEXTROSE	A	Only to be used in a medicine where Danisco Australia Pty Ltd (Client ID 54247), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 2 March 2022. Only permitted for use in medicines: - limited to oral routes of administration; and - when the maximum recommended daily dose does not provide more than 15g of hydrogenated polydextrose.
2615	HYDROGENATED POLYISOBUTENE	E	Only for use in topical medicines for dermal application.
2616	HYDROGENATED SOYA OIL	E	
2617	HYDROGENATED TALLOW GLYCERIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
2618	HYDROGENATED VEGETABLE OIL	E	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2619	HYDROLIAC	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2620	HYDROLYSED ADANSONIA DIGITATA LEAF POLYSACCHARIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%
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	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%.
2623	HYDROLYSED COLLAGEN	A, E	
2624	HYDROLYSED ELASTIN	E	Only for use in topical medicines for dermal application.
2625	HYDROLYSED GELATIN	A, E	

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2626	HYDROLYSED GLYCOSAMINOGLYCANS	E	Only for use in topical medicines for dermal application.
2627	HYDROLYSED JOJOBA ESTERS	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2628	HYDROLYSED KERATIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2629	HYDROLYSED MAIZE STARCH	E	
2630	HYDROLYSED MILK PROTEIN	E	
2631	HYDROLYSED RICE	A, E, H	
2632	HYDROLYSED RICE PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.125%.
2633	HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2634	HYDROLYSED VEGETABLE PROTEIN	E	
2635	HYDROLYSED WHEAT PROTEIN	E	Gluten is a mandatory component of hydrolysed wheat protein.
2636	HYDROLYSED WHEAT PROTEIN/PVP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.2%.
2637	HYDROLYSED YEAST PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
2638	HYDROQUINONE DIMETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2639	HYDROUS WOOL FAT	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2640	HYDROXOCOBALAMIN	A	
2641	HYDROXYACETOPHENONE	E	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%.
2642	HYDROXYAPATITE	A, E	
2643	HYDROXYCITRATE COMPLEX	A	Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.
2644	HYDROXYCITRIC ACID	A	
2645	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%.
2646	HYDROXYCITRONELLAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2647	HYDROXYCITRONELLAL-METHYLANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2648	HYDROXYCITRONELLOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2649	HYDROXYETHYL CETEARAMIDOPROPYLDIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
2650	HYDROXYETHYL UREA	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration must be no more than 1%.
2651	HYDROXYLATED LANOLIN	E	
2652	HYDROXYLATED MILK GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 0.1%.
2653	HYDROXYLYSINE	A, E	
2654	HYDROXYMETHYLCELLULOSE	E	
2655	HYDROXYOCTACOSANYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
2656	HYDROXYPALMITOYL SPHINGANINE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 0.1%.
2657	HYDROXYPROLINE	A, E	
2658	HYDROXYPROPYL DISTARCH PHOSPHATE	E	Only permitted for: - use in topical medicines for dermal application; and - medicines for internal use. When for use in topical medicines for dermal application: - not to be included medicines intended for use in the eye or damaged skin; and - the concentration of hydroxypropyl distarch phosphate in the medicine must

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			be no more than 4%. When for internal use, the maximum recommended daily dose must not contain more than 240mg of hydroxypropyl distarch phosphate.
2659	HYDROXYPROPYL STARCH	E	
2660	HYDROXYPROPYLBETADEX	E	Only for use in topical medicines for dermal application.
2661	HYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 9%.
2662	HYETELLOSE	E	
2663	HYLOCEREUS LEMAIREI	E	Permitted for use only as a colour for oral and topical use.
2664	HYLOCEREUS UNDATUS	A, H	
2665	HYMETELLOSE	E	
2666	HYOSCYAMUS LEAF DRY	A, H	Alkaloids calculated as hyoscyamine and hyoscine are mandatory components of Hyoscamus leaf dry. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of hyoscine in the medicine must be no more than than 300 micrograms/kg or 300 micrograms/L or 0.00003%.

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2667	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%.
2668	HYOSCYAMUS NIGER	A, H	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%.
2669	HYPERICUM ASCYRON	A, H	
2670	HYPERICUM JAPONICUM	A, H	
2671	HYPERICUM PERFORATUM	A, E, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2672	HYPROLOSE	E	
2673	HYPROMELLOSE	E	
2674	HYPROMELLOSE PHTHALATE	E	
2675	HYPTIS SUAVEOLENS	A, H	
2676	HYSSOPUS OFFICINALIS	A, E, H	
2677	IBERIS AMARA	A, H	
2678	ICHTHAMMOL	H	Only for use as an active homoeopathic ingredient.
2679	ILEX AQUIFOLIUM	A, H	
2680	ILEX CHINENSIS	A, H	
2681	ILEX PARAGUARIENSIS	A, E, H	Caffeine is a mandatory component of Ilex paraguariensis. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is released for supply after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			before 2 September 2019; and - is released for supply before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (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.'

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
2682	ILEX ROTUNDA	A, H	
2683	ILEX VERTICILLATA	A, H	
2684	ILLICIUM VERUM	A, H	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).

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2685	IMIDUREA	E	Only for use in topical medicines for dermal application.
2686	IMMORTELLE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2687	IMMORTELLE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2688	IMPATIENS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2689	IMPATIENS BALSAMINA	A, H	
2690	IMPATIENS GLANDULIFERA	A, H	
2691	IMPERATA CYLINDRICA	A, E, H	
2692	INDIGO CARMINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			administration.
2693	INDIGO CARMINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2694	INDIGOFERA TINCTORIA	A, H	
2695	INDISAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2696	INDOLE	E, H	Only for use as an active homoeopathic or excipient ingredient. The maximum recommended daily dose must contain no more than 75 mg indole.
2697	INDOLENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2698	INDUSTRIAL METHYLATED SPIRIT	E	
2699	INOSITOL	A, E	
2700	INULA BRITANNICA	A, H	
2701	INULA HELENIUM	A, E, H	
2702	INULA RACEMOSA	A, H	
2703	INULIN	A, E	

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2704	INULIN LAURYL CARBAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1.2%.
2705	INVERT SUGAR	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
2706	INVERT SYRUP	E	Glucose is a mandatory component of Invert syrup when the route of administration is oral or sublingual. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar,

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
2707	IODINE	H	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.
2708	IODOPROPYNYL BUTYLCARBAMATE	E	For use as an excipient ingredient in topical medicines only. The concentration in aqueous medicines must be no more than 10%.
2709	IONONE	E	Permitted for use only: (a) in topical medicines for

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
2710	IOPAMIDOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2711	IPECACUANHA DRY	A, H	Emetine is a mandatory component of Ipecacuanha Dry. The concentration of emetine in the medicine must be no more than 0.2%.
2712	IPECACUANHA POWDER	A, H	Emetine is a mandatory component of Ipecacuanha Powder. The concentration of emetine in the medicine must be no more than 0.2%.
2713	IPECACUANHA PREPARED	A, H	Emetine is a mandatory component of Ipecacuanha Prepared. The concentration of emetine in the medicine must be no more than 0.2%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2714	IPECACUANHA ROOT LIQUID EXTRACT	A, H	Emetine is a mandatory component of Ipecacuanha root liquid extract. The concentration of emetine in the medicine must be no more than 0.2%.
2715	IPOMOEA BATATAS	A, H	
2716	IPOMOEA JALAPA	A, H	
2717	IRIDOPHYCUS FLACCIDUM	A, H	Iodine is a mandatory component of Iridophycus flaccidum. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2718	IRIS DOMESTICA	A, H	
2719	IRIS FLORENTINA	A, H	
2720	IRIS GERMANICA	A, H	
2721	IRIS PALLIDA	A, H	
2722	IRIS TENAX	H	
2723	IRIS VERSICOLOR	A, H	
2724	IRON	A, H	Only for use in oral medicines. When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2725	IRON (II) BISGLYCINE SULFATE TRIHYDRATE	A	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2726	IRON (II) GLYCINATE	A	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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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 (III) GLYCINATE	A	Only for use in oral medicines. Iron is a mandatory component of iron (III) glycinate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2728	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

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2729	IRON OXIDE BLACK	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.
2730	IRON OXIDE RED	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.
2731	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,

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			the concentration in the medicine must be no more than 10 mg per dosage unit.
2732	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 (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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
2733	IRONE	E	
2734	IRVINGIA GABONENSIS SEED TRIGLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 0.375%.
2735	ISATIS TINCTORIA	A, H	
2736	ISOAMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2737	ISOAMYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2738	ISOAMYL ACETATE	E	Permitted for use only in combination with other

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2739	ISOAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2740	ISOAMYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2741	ISOAMYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more 1%.
2742	ISOAMYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2743	ISOAMYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2744	ISOAMYL CITRONELLYL KETONE	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%.
2745	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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2746	ISOAMYL HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2747	ISOAMYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2748	ISOAMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2749	ISOAMYL LAURATE	E	Only for use in topical

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2750	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: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2751	ISOAMYL PHENYLACETATE	E	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%.
2752	ISOAMYL PHENYLETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
2753	ISOAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2754	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%.
2755	ISOBERGAMIATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2756	ISOBORNEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2757	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%.
2758	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%.
2759	ISOBUTANE	E	Only for use in topical medicines for dermal application.
2760	ISOBUTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more 1%.
2761	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.
2762	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%.
2763	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%.
2764	ISOBUTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2765	ISOBUTYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%.
2766	ISOBUTYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2767	ISOBUTYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2768	ISOBUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application. Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
2769	ISOBUTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2770	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%.
2771	ISOBUTYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2772	ISOBUTYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2773	ISOBUTYL QUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2774	ISOBUTYL SALICYLATE	E	Only for use in topical medicines for dermal application.
2775	ISOBUTYLENE/ISOPRENE COPOLYMER	E	Only for oral use when the dosage form is chewing gum. The concentration must be consistent with best practice for the production of gum delivery systems.
2776	ISOBUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2777	ISOBUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2778	ISOCETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2779	ISOCETYL LINOLEOYL	E	Only for use in topical

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	STEARATE		medicines for dermal application.
2780	ISOCETYL STEARATE	E	Only for use in topical medicines for dermal application.
2781	ISOCETYL STEAROYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 10%.
2782	ISOCYCLOCITRAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2783	ISODECYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
2784	ISODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2785	ISODECYL OLEATE	E	Only for use in topical medicines for dermal application.
2786	ISODECYL SALICYLATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			more than 2%.
2787	ISODODECANE	E	Only for use in topical medicines for dermal application.
2788	ISOEICOSANE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 2%.
2789	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%.
2790	ISOEUGENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2791	ISOEUGENYL BENZYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2792	ISOHEXADECANE	E	Only for use in topical medicines for dermal application.
2793	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%.
2794	ISOLEUCINE	A, E	
2795	ISOMALT	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]'.
2796	ISOMENTHONE	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
2797	ISOMETHYLIONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2798	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%.
2799	ISONONYL ISONONANOATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 15%.
2800	ISOPENTANE	E	For dental use only. The concentration must be no more than 2%.

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2801	ISOPENTANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2802	ISOPHORONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2803	ISOPHYTOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2804	ISOPROPYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other 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

Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
2805	ISOPROPYL 4-HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application. Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
2806	ISOPROPYL ACETATE	E	Only for use in topical medicines for dermal application.
2807	ISOPROPYL ALCOHOL	E	
2808	ISOPROPYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2809	ISOPROPYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2810	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
2811	ISOPROPYL LANOLATE	E	Only for use in topical medicines for dermal application.
2812	ISOPROPYL LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 5.6%.
2813	ISOPROPYL MYRISTATE	E	
2814	ISOPROPYL PALMITATE	E	Only for use in topical medicines for dermal application.
2815	ISOPROPYL PPG-2 ISODECETH-7 CARBOXYLATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 10%.
2816	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2817	ISOPROPYL TITANIUM TRIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 0.2%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2818	ISOPROPYL-3-METHYL-BUTANE THIOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2819	ISOPULEGOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2820	ISORALDEINE 70	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2821	ISOSTEARIC ACID	E	Only for use in topical medicines for dermal application.
2822	ISOSTEAROYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 0.3%.

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

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2823	ISOSTEARYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2824	ISOSTEARYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2825	ISOSTEARYL PALMITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 2%.
2826	ISOTRIDECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2827	ISOVALERALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2828	ISOVALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2829	ISPAGHULA HUSK DRY	A, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. (a) 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). The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated, the following warning statement is required on the label: - (PSYLL) 'On medical advice' (or words to that effect).

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2830	ISPAGHULA HUSK POWDER	A, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. (a) 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). The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated, the following warning statement is required on the label: - (PSYLL) 'On medical advice' (or words to that effect).
2831	IVA AXILLARIS	A, H	
2832	JAMAICA DOGWOOD BARK DRY	A, H	
2833	JAMAICA DOGWOOD BARK POWDER	A, H	
2834	JASMINE ABSOLUTE	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2835	JASMINE LACTONE	E	Only for use in topical medicines for dermal application.
2836	JASMINE OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2837	JASMINUM GRANDIFLORUM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2838	JASMINUM OFFICINALE	A, E, H	
2839	JASSOLIA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Volume 3

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2840	JATEORHIZA PALMATA	A, H	
2841	JATROPHA CURCAS	H	Only for use as an active homoeopathic ingredient
2842	JERUSALEM ARTICHOKE	E	
2843	JOJOBA ESTERS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 25%.
2844	JUGLANS CINEREA	A, E, H	
2845	JUGLANS NIGRA	A, E, H	
2846	JUGLANS REGIA	A, H	
2847	JUNCUS EFFUSUS	A, H	
2848	JUNIPER BERRY OIL	A, E, H	
2849	JUNIPER BERRY OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2850	JUNIPERUS CALIFORNICA	A, H	
2851	JUNIPERUS COMMUNIS	A, E, H	
2852	JUNIPERUS DEPPEANA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2853	JUNIPERUS OXYCEDRUS	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2854	JUNIPERUS VIRGINIANA	A, E, H	
2855	JUSTICIA ADHATODA	A, H	