Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2019

This instrument is in 6 volumes:

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**
2145	FABIANA IMBRICATA	A, H	
2146	FAGOPYRUM ESCULENTUM	A, H	
2147	FAGUS GRANDIFOLIA	A, H	
2148	FAGUS SYLVATICA	A, H	
2149	FALLOPIA MULTIFLORA	A, H	When for oral use, the medicine requires the following warning statement on the medicine label: - (FALLMUL) 'Warning: Fallopia multiflora may harm the liver in some people. Use under the supervision of a healthcare professional.'
2150	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%.
2151	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%.
2152	FAST GREEN FCF	E	Permitted for use only as a colour for oral and topical use.
2153	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%.
2154	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%.

2155	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%.
2156	FENNEL BITTER SEED DRY	A, E, H	When used in oral medicines and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statements on the medicine 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 used in oral medicines and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statements on the medicine label if supplied after 1 April 2019: - (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.'
2157	FENNEL LEAF	E	
2158	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 medicine requires the following warning statement on the medicine 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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statements on the medicine 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 used in oral medicines and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statements on the medicine label if supplied after 1 April 2019: - (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.'
2159	FENNEL SWEET SEED DRY	A, E, H	When used in oral medicines and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statements on the medicine 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 used in oral medicines

			and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statements on the medicine label if supplied after 1 April 2019: - (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.'
2160	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%.
2161	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%.
2162	FERRIC AMMONIUM CITRATE	A, E, H	When for internal use, iron is a mandatory component of ferric ammonium citrate. When for internal use, the

		medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are 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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: - (IRONDEF) 'Not for the

			treatment of iron deficiency conditions' (or words to that effect). 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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2163	FERRIC CHLORIDE	A, E, H	When for internal use, iron is a mandatory component of ferric chloride. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a

			quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are 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).
2164	FERRIC CHLORIDE HEXAHYDRATE	A, E, H	When for internal use, iron is a mandatory component of ferric chloride hexahydrate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when

			used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are 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).
2165	FERRIC GLYCEROPHOSPHATE	A, E, H	When for internal use, iron is a mandatory component of ferric

		glycerophosphate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are 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).
2166	FERRIC OXIDE	E	
2167	FERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2168	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 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).
2169	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.
2170	FERROSOFERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2171	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 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).

2172	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 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).
2173	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 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).
2174	FERROUS IODIDE	H	Only for use as an active homoeopathic ingredient.
2175	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 treatment of iron deficiency conditions' (or words to that effect).
2176	FERROUS PHOSPHATE OCTAHYDRATE	A, E, H	When for internal use, iron is a mandatory component of ferrous phosphate octahydrate. When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding

			up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2177	FERROUS PICRATE	H	Only for use as an active homoeopathic ingredient.

2178	FERROUS SULFATE	A, E, H	When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron

			deficiency conditions' (or words to that effect).
2179	FERROUS SULFATE HEPTAHYDRATE	A, E, H	When for internal use, iron is a mandatory component of ferrous sulfate heptahydrate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional

			support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2180	FERULA ASSA-FOETIDA	A, E, H	
2181	FERULA FOETIDA	A, E, H	
2182	FERULA GALBANIFLUA	A, E, H	
2183	FERULA RUBRICAULIS	A, E, H	
2184	FERULA SUMBUL	A, H	
2185	FERULIC ACID	E	Only for use in topical medicines for dermal application.
2186	FESTUCA ELATIOR	A, H	
2187	FEVERFEW HERB DRY	A, H	
2188	FEVERFEW HERB POWDER	A, H	
2189	FICUS CARICA	A, E, H	
2190	FICUS PUMILA	A, H	
2191	FIG	E	
2192	FIG DRY	A, H	
2193	FILIPENDULA ULMARIA	A, H	Methyl salicylate is a mandatory component of Filipendula ulmaria. Not to be included in

		medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage 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. In addition, when the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements

		under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b). a) The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and 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); - (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).

2194	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%.
2195	FIR NEEDLE OIL CANADIAN	A, E	
2196	FIR NEEDLE OIL SIBERIAN	A, E	
2197	FIRMIANA SIMPLEX	A, E, H	
2198	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2199	FLEMINGIA MACROPHYLLA	A, H	
2200	FLOUVE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2201	FLUORESCEIN SODIUM	E	
2202	FOENICULUM VULGARE	A, E, H	When used in oral medicines and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statements on the medicine 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 used in oral medicines and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statements on the medicine label if supplied after 1 April 2019: - (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 fitted on the container, and the medicine requires the following warning statement

			on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
2203	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)'.
2204	FOOD ORANGE 6	E	Permitted for use only as a

			colour for oral and topical use.
2205	FOOD ORANGE 7	E	Permitted for use only as a colour for oral and topical use.
2206	FOOD RED 13	E	Permitted for use only as a colour for topical use.
2207	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%.
2208	FORMIC ACID	H	Only for use as an active homoeopathic ingredient.
2209	FORSYTHIA SUSPENSA	A, H	
2210	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'.
2211	FRACTIONATED COCONUT OIL	E	
2212	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.
2213	FRAGARIA CHILOENSIS	A, E, H	
2214	FRAGARIA VESCA	A, E, H	
2215	FRAGARIA VIRGINIANA	A, E, H	
2216	FRAGARIA X ANANASSA	A, E, H	
2217	FRANGULA BARK DRY	A, H	Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that

			effect]. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' [or words to that effect]. When not promoted or marketed as laxative, the medicine requires 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'.
2218	FRANGULA BARK POWDER	A, H	Glucofrangulins calculated as

		glucofrangulin A is a mandatory component of Frangula bark powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]'. 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'.
2219	FRANGULA PURSHIANA	A, H	When for oral use, hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of Frangula purshiana. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems';

	and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect]. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' [or words to that effect]. When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of

			water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
2220	FRAXINUS AMERICANA	A, H	
2221	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A, H	
2222	FRAXINUS EXCELSIOR	A, H	The components Nuzhenide and secoiridoid glucoside GL3 are only available when the plant part is seed.
2223	FRAXINUS ORNUS	A, H	
2224	FRITILLARIA CIRRHOSA	A, H	
2225	FRITILLARIA THUNDBERGII	A, H	
2226	FRITILLARIA VERTICILLATA	A, H	
2227	FRUCTOOLIGOSACCHARIDES	A, E	
2228	FRUCTOSE	A, E, H	
2229	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.

2230	FUMARIA OFFICINALIS	A, E, H	
2231	FUMARIC ACID	E, H	Only for use as an active homoeopathic or excipient ingredient.
2232	FUMITORY HERB DRY	A, H	
2233	FUMITORY HERB POWDER	A, H	
2234	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%.
2235	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%.
2236	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%.
2237	FURFURYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2238	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%.
2239	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%.
2240	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%.
2241	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%.
2242	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%.
2243	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%.
2244	GALEGA OFFICINALIS	A, H	
2245	GALEOPSIS SEGETUM	A, H	

2246	GALIUM APARINE	A, H	
2247	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%.
2248	GALIUM PALUSTRE	A, H	
2249	GALIUM VERUM	A, H	
2250	GALL STONE	H	Only for use as an active homoeopathic ingredient.
2251	GALPHIMIA GLAUCA	A, H	
2252	GAMMA-4-DIMETHYL-3-CYCLOHEXENE-1-PROPANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2253	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%.
2254	GAMMA-CYCLODEXTRIN	E	

2255	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%.
2256	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%.
2257	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%.

2258	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%.
2259	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%.
2260	GAMMA-LINOLEIC ACID	E	Only for use in topical medicines for dermal application.
2261	GAMMA-LINOLENIC ACID	E	
2262	GAMMA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2263	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%.
2264	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%.
2265	GAMMA-TERPINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

			medicine must be no more 1%.
2266	GAMMA-TOCOPHEROL	E	
2267	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%.
2268	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%.
2269	GANODERMA LUCIDUM	A, E, H	
2270	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.
2271	GARCINIA QUAESITA	A, H	

2272	GARDEN BEAN	E	
2273	GARDENIA JASMINOIDES	A, E	
2274	GARDENIA TAHITENSIS FLOWER EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%
2275	GARLIC BULB DRY	A, E, H	
2276	GARLIC BULB FRESH	A, H	
2277	GARLIC BULB POWDER	A, E, H	
2278	GARLIC CLOVE POWDER	A, H	
2279	GARLIC OIL	A, E, H	
2280	GASTRODIA ELATA	A, H	
2281	GAULTHERIA PROCUMBENS	A, E, H	Methyl salicylate is a mandatory component of Gaultheria procumbens. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.

		When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. In addition, when the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b). a) The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that

			effect). b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and 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); - (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
2282	GELATIN	A, E	
2283	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.
2284	GELLAN GUM	E	
2285	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%.
2286	GELSEMIUM POWDER	A, H	
2287	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%.
2288	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%.
2289	GENTIAN DRY	A, H	
2290	GENTIAN POWDER	A, H	
2291	GENTIANA LUTEA	A, E, H	
2292	GENTIANA MACROPHYLLA	A, H	
2293	GENTIANA RHODANTHA	A, H	

2294	GENTIANA SCABRA	A, H	
2295	GENTIANELLA AMARELLA	A, H	
2296	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%.
2297	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%.
2298	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%.
2299	GERANIUM	E	Permitted for use only in combination with other permitted ingredients as a

			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2300	GERANIUM MACULATUM	A, E, H	
2301	GERANIUM OIL	A, E, H	
2302	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%.
2303	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%.
2304	GERANIUM ROBERTIANUM	A, E, H	
2305	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%.

2306	GERANIUM SIBIRICUM	A, E, H	
2307	GERANYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2308	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%.
2309	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%.

2310	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%.
2311	GERANYL ETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2312	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%.
2313	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%.
2314	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%.
2315	GERANYL NITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2316	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%.
2317	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%.
2318	GEUM RIVALE	A, H	
2319	GEUM URBANUM	A, H	
2320	GHATTI GUM	A, E, H	
2321	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 300 micrograms of iodine per maximum recommended daily dose.
2322	GINGER DRY	A, E, H	
2323	GINGER OIL	A, E, H	
2324	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%.
2325	GINGER POWDER	A, E, H	
2326	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.
2327	GLACIAL ACETIC ACID	E, H	The concentration in the medicine must be no more than 1.5%.
2328	GLECHOMA HEDERACEA	A, H	
2329	GLECHOMA LONGITUBA	A, H	
2330	GLEDITSIA AUSTRALIS	A, H	
2331	GLEDITSIA SINENSIS	A, H	
2332	GLEHNIA LITTORALIS	A, H	
2333	GLORIOSA SUPERBA	A, H	Colchicine is a mandatory component of Gloriosa superba and must be declared in the application. The concentration of colchicine in the product must be no more

			than 10 mg/kg or 10 mg/L or 0.001%.
2334	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2335	GLUCONOLACTONE	E	
2336	GLUCOSAMINE HYDROCHLORIDE	A, E	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2337	GLUCOSAMINE SULFATE	A	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2338	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 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.’
2339	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2340	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).

2341	GLUCOSE GLUTAMATE	E	Only for use in topical medicines for dermal application.
2342	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).
2343	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%.

2344	GLUTAMIC ACID	A, E	Only for use in topical medicines for dermal application.
2345	GLUTAMIC ACID HYDROCHLORIDE	A, E, H	
2346	GLUTAMINE	A, E, H	
2347	GLUTARAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2348	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).
2349	GLUTEN-FREE WHEAT STARCH	E	
2350	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%.
2351	GLYCEROL	A, E	When used as an active ingredient, it is only for use in topical medicines for dermal application.
2352	GLYCEROL ESTER OF PARTIALLY HYDROGENATED GUM ROSIN	E	Only for use when the dosage form is 'chewing gum'. Must comply with: a) the Glycerol Ester of Partially Hydrogenated Gum Rosin monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia-National Formulary, as in force or existing from time to time.
2353	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%.
2354	GLYCERYL CAPRYLATE	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%.
2355	GLYCERYL DIISOSTEARATE	E	For use in topical medicines for dermal application.
2356	GLYCERYL DILAURATE	E	Only for use in topical medicines for dermal application.
2357	GLYCERYL DIOLEATE	E	Only for use in topical medicines for dermal application.
2358	GLYCERYL DISTEARATE	E	Only for use in topical medicines for dermal application.
2359	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%.
2360	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%.
2361	GLYCERYL LAURATE	E	Only for use in topical medicines for dermal application.
2362	GLYCERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2363	GLYCERYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2364	GLYCERYL MONOOLEATE	E	
2365	GLYCERYL MONOSTEARATE	E	
2366	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2367	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.
2368	GLYCERYL PALMITO-STEARATE	E	
2369	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%.
2370	GLYCERYL POLYMETHACRYLATE	E	Only for use in topical medicines for dermal application.
2371	GLYCERYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2372	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.
2373	GLYCERYL SORBITAN OLEOSTEARATE	E	Only for use in topical medicines for dermal application.
2374	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.
2375	GLYCERYL STEARATE CITRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
2376	GLYCERYL TRIACETYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 6%.
2377	GLYCERYL TRIACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.

2378	GLYCERYL TRINITRATE	H	Only for use as an active homoeopathic ingredient.
2379	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%.
2380	GLYCINE	A, E	
2381	GLYCINE MAX	A, E, H	
2382	GLYCOGEN	E	Only for use in topical medicines for dermal application.
2383	GLYCOL DISTEARATE	E	Only for use in topical medicines for dermal application.
2384	GLYCOLIC ACID	E	Only for use in topical medicines for dermal application. Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose. When present as an excipient in sunscreens, the concentration in the medicine

			must be no more than 5%. When used as an excipient 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.
2385	GLYCYRRHIZA GLABRA	A, E, H	
2386	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%.
2387	GLYCYRRHIZA URALENSIS	A, E, H	
2388	GLYCYRRHIZINIC ACID	E	
2389	GNAPHALIUM AFFINE	A, H	
2390	GNAPHALIUM POLYCEPHALUM	A, H	
2391	GNAPHALIUM ULIGINOSUM	A, H	
2392	GOAT	H	Only for use as an active homoeopathic ingredient.
2393	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).
2394	GOLD	E, H	Only for use as an active homoeopathic or excipient ingredient.
2395	GOLD CHLORIDE	H	Only for use as an active homoeopathic ingredient.
2396	GOLDEN ROD HERB DRY	A, E, H	
2397	GOLDEN SEAL ROOT DRY	A, H	
2398	GOLDEN SEAL ROOT POWDER	A, H	
2399	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).
2400	GOMPHRENA GLOBOSA	A, H	
2401	GOOSEBERRY	E	
2402	GOSSYPIUM HERBACEUM	A, E, H	
2403	GRAPE	E	
2404	GRAPE SEED OIL	E	
2405	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'
2406	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'

2407	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'
2408	GRAPEFRUIT	E	
2409	GRAPEFRUIT OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2410	GRAPEFRUIT OIL COLDPRESSED	A, E, H	
2411	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%.
2412	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%.
2413	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%.
2414	GRAPHITE	H	Only for use as an active homoeopathic ingredient.
2415	GRATIOLA LINIFOLIA	A, H	
2416	GREATER NETTLE HERB DRY	A, H	
2417	GREATER NETTLE HERB POWDER	A, H	
2418	GREATER NETTLE ROOT DRY	A, H	
2419	GREATER NETTLE ROOT POWDER	A, H	
2420	GREEN LIPPED MUSSEL	A	
2421	GREEN LIPPED MUSSEL DRIED	A	
2422	GREEN LIPPED MUSSEL OIL	A	

2423	GREEN S	E	Only for use as a colour in topical and oral medicines.
2424	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.'
2425	GRINDELIA CAMPORUM	A, H	
2426	GRINDELIA ROBUSTA	A, H	
2427	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%.
2428	GROUND IVY HERB DRY	A, H	
2429	GROUND IVY HERB POWDER	A, H	
2430	GUAIAC WOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

			medicine must be no more 1%.
2431	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%.
2432	GUAIACUM OFFICINALE	A, E, H	
2433	GUAIACUM RESIN	A, E, H	
2434	GUAIACUM SANCTUM	A, H	
2435	GUAIACWOOD 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 than 1%.
2436	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%.

2437	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%.
2438	GUANINE	E	Only for use as an excipient in topical medicines for dermal application.
2439	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.
2440	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).
2441	GUAR GUM	A, E, H	
2442	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	E	Only for use as an excipient in topical medicines for dermal application.
2443	GUAREA RUSBYI	A, H	
2444	GUAVA	E	
2445	GURJUN BALSAM	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2446	GYMNADENIA NIGRA	A	
2447	GYMNEMA SYLVESTRE	A, H	
2448	GYMNOCLADUS DIOICA	A, H	
2449	GYNOSTEMMA PENTAPHYLLUM	A	The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).
2450	GYNURA JAPONICA	A, H	

2451	HAHNEMANN'S SOLUBLE MERCURY	H	Only for use as an active homoeopathic ingredient.
2452	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 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.'
2453	HAMAMELIS LEAF DRY	A, H	
2454	HAMAMELIS LEAF POWDER	A, H	
2455	HAMAMELIS VIRGINIANA	A, E, H	
2456	HAMAMELIS WATER	A, E, H	
2457	HANDROANTHUS HEPTAPHYLLUS	A, H	
2458	HANDROANTHUS IMPETIGINOSUS	A, E, H	
2459	HARD FAT	E	
2460	HARD PARAFFIN	E	
2461	HARICOT BEAN	E	
2462	HARPAGOPHYTUM PROCUMBENS	A, E, H	
2463	HARUNGANA MADAGASCARIENSIS	A, H	
2464	HAZEL NUT	E	
2465	HAZEL NUT OIL	E	
2466	HEAVY KAOLIN	E	
2467	HEAVY MAGNESIUM OXIDE	A, E, H	

2468	HECTORITE	E	Only for use in topical medicines for dermal application.
2469	HEDEOMA PULEGIOIDES	A	
2470	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%.
2471	HEDTA	E	Only for use as an excipient in topical medicines for dermal application.
2472	HEKLA LAVA	H	Only for use as an active homoeopathic ingredient.
2473	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%.
2474	HELIANTHEMUM NUMMULARIUM	A, H	
2475	HELIANTHUS ANNUUS	A, E, H	
2476	HELIANTHUS TUBEROSUS	A, H	
2477	HELICHRYSUM ANGUSTIFOLIUM	A, E, H	

2478	HELICHRYSUM ARENARIUM	A, H	
2479	HELIOTROPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2480	HELLEBORUS NIGER	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2481	HELLEBORUS VIRIDIS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2482	HELONIAS RHIZOME DRY	A, H	
2483	HELONIAS RHIZOME POWDER	A, H	
2484	HEMIDESMUS INDICUS	A, E, H	
2485	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%.

2486	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%.
2487	HEPTANOIC 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%.
2488	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%.
2489	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%.

2490	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%.
2491	HEPTYL UNDECYLENATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of the medicine must be no more than 25%.
2492	HERACLEUM HEMSLEYANUM	A, H	
2493	HERNIARIA GLABRA	A, H	
2494	HESPERIDIN	A, E	
2495	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%.
2496	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%.
2497	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%.
2498	HEXAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2499	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.

2500	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%.
2501	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%.
2502	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 %.

2503	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%.
2504	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%.
2505	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%.
2506	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%.
2507	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%.
2508	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%.
2509	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%.
2510	HEXYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

			medicine must be no more than 1%.
2511	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2512	HEXYL NICOTINATE	E	
2513	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%.
2514	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%.
2515	HEXYLDECANOL	E	Only for use as an excipient in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration of the medicine must be no more than 3%.
2516	HEXYLENE GLYCOL	E	Only for use as an excipient in

			topical medicines for dermal application.
2517	HIBISCUS ESCULENTUS	A, H	
2518	HIBISCUS MUTABILIS	A, H	
2519	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%.
2520	HIBISCUS SABDARIFFA	A, E, H	
2521	HIERACIUM PILOSELLA	A, H	
2522	HIGH AMYLOSE MAIZE STARCH	A, E, H	
2523	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.
2524	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%.
2525	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.
2526	HIGH SELENIUM YEAST	A	When for oral or sublingual use, selenium is a mandatory component of high selenium yeast. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
2527	HIMATANTHUS LANCIFOLIUS	A, E, H	
2528	HIPPOPHAE RHAMNOIDES	A, E, H	
2529	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%.
2530	HISTAMINE DIHYDROCHLORIDE	H	Only for use as an active homoeopathic ingredient.
2531	HISTIDINE	A	
2532	HISTIDINE HYDROCHLORIDE	A, E, H	
2533	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%.
2534	HO WOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

2535	HOLCUS LANATUS	A, H	
2536	HOLY THISTLE HERB DRY	A, H	
2537	HOLY THISTLE HERB POWDER	A, H	
2538	HOMALOMENA OCCULTA	A, H	
2539	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 be no more than 15%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July

			2019: - (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).
2540	HONEY	A, E	When the route of administration is oral, the medicine requires the following warning statement on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). 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).
2541	HONEY BEE	H	Only for use as an active homoeopathic ingredient.
2542	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, 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.
2543	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%.
2544	HOP STROBILE DRY	A, H	
2545	HOP STROBILE POWDER	A, H	
2546	HOPS OIL	A, E, H	
2547	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. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
2548	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. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.

2549	HOREHOUND EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2550	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).
2551	HOTTONIA PALUSTRIS	A, H	
2552	HOUTTUYNIA CORDATA	A, H	
2553	HOVENIA DULCIS	A, H	
2554	HUMULUS LUPULUS	A, E, H	
2555	HYALURONIC ACID	E	Only for use as an excipient in topical medicines for dermal application.
2556	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.
2557	HYDRANGEA ARBORESCENS	A, H	

2558	HYDRANGEA PANICULATA	A, H	
2559	HYDRASTIS CANADENSIS	A, E, H	
2560	HYDRATED SILICA	E	Only for use when the route of administration is other than inhalation.
2561	HYDROCHLORIC ACID	E	The concentration of the medicine must be no more than 0.5%.
2562	HYDROCOTYLE UMBELLATA	A, H	
2563	HYDROFLUORIC ACID	H	Only for use as an active homoeopathic ingredient.
2564	HYDROGEN CYANIDE	H	Only for use as an active homoeopathic ingredient.
2565	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.

2566	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%.
2567	HYDROGENATED C6-14 OLEFIN POLYMERS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
2568	HYDROGENATED CASTOR OIL	E	
2569	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%.
2570	HYDROGENATED COCONUT OIL	E	
2571	HYDROGENATED COTTONSEED OIL	E	
2572	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.
2573	HYDROGENATED ETHYLENE/PROPYLENE/STYRENE COPOLYMER	E	The combined concentration of hydrogenated ethylene/propylene/styrene copolymer must be no more than 9%.
2574	HYDROGENATED LANOLIN	E	
2575	HYDROGENATED LECITHIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2576	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%.
2577	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%.
2578	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%.
2579	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.
2580	HYDROGENATED POLYDECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
2581	HYDROGENATED POLYISOBUTENE	E	Only for use in topical medicines for dermal application.
2582	HYDROGENATED SOYA OIL	E	
2583	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%.
2584	HYDROGENATED VEGETABLE OIL	E	
2585	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%.
2586	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%
2587	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%

2588	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%.
2589	HYDROLYSED COLLAGEN	A, E	
2590	HYDROLYSED ELASTIN	E	Only for use in topical medicines for dermal application.
2591	HYDROLYSED GELATIN	A, E	
2592	HYDROLYSED GLYCOSAMINOGLYCANS	E	Only for use in topical medicines for dermal application.
2593	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%.
2594	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%.

2595	HYDROLYSED MAIZE STARCH	E	
2596	HYDROLYSED MILK PROTEIN	E	
2597	HYDROLYSED RICE	A, E, H	
2598	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%.
2599	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%.
2600	HYDROLYSED VEGETABLE PROTEIN	E	
2601	HYDROLYSED WHEAT PROTEIN	E	When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
2602	HYDROLYSED WHEAT	E	Only for use in topical medicines for dermal

	PROTEIN/PVP CROSSPOLYMER		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%.
2603	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%.
2604	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%.
2605	HYDROUS WOOL FAT	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.

2606	HYDROXOCOBALAMIN	A	
2607	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%.
2608	HYDROXYAPATITE	A, E	
2609	HYDROXYCITRATE COMPLEX	A	Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.
2610	HYDROXYCITRIC ACID	A	
2611	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%.
2612	HYDROXYCITRONELLAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2613	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%.
2614	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%.
2615	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%.

2616	HYDROXYETHYL UREA	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 1%.
2617	HYDROXYLATED LANOLIN	E	
2618	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%.
2619	HYDROXYLYSINE	A, E	
2620	HYDROXYMETHYLCELLULOSE	E	
2621	HYDROXYOCTACOSANYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
2622	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%.
2623	HYDROXYPROLINE	A, E	

2624	HYDROXYPROPYL DISTARCH PHOSPHATE	E	Only permitted for: - use in topical medicines for dermal application; and - medicines for internal use. When for use in topical medicines for dermal application: - not to be included medicines intended for use in the eye or damaged skin; and - the concentration of hydroxypropyl distarch phosphate in the medicine must be no more than 4%. When for internal use, the maximum recommended daily dose must not contain more than 240mg of hydroxypropyl distarch phosphate.
2625	HYDROXYPROPYL STARCH	E	
2626	HYDROXYPROPYLBETADEX	E	Only for use in topical medicines for dermal application.
2627	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%.
2628	HYETELLOSE	E	

2629	HYLOCEREUS LEMAIREI	E	Permitted for use only as a colour for oral and topical use.
2630	HYLOCEREUS UNDATUS	A, H	
2631	HYMETELLOSE	E	
2632	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 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2633	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%.

2634	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%.
2635	HYPERICUM ASCYRON	A, H	
2636	HYPERICUM JAPONICUM	A, H	
2637	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.'
2638	HYPROLOSE	E	
2639	HYPROMELLOSE	E	
2640	HYPROMELLOSE PHTHALATE	E	
2641	HYPTIS SUAVEOLENS	A, H	
2642	HYSSOPUS OFFICINALIS	A, E, H	
2643	IBERIS AMARA	A, H	
2644	ICHTHAMMOL	H	Only for use as an active homoeopathic ingredient.

2645	ILEX AQUIFOLIUM	A, H	
2646	ILEX CHINENSIS	A, H	
2647	ILEX PARAGUARIENSIS	A, E, H	Caffeine is a mandatory component of Ilex paraguariensis. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
2648	ILEX ROTUNDA	A, H	
2649	ILEX VERTICILLATA	A, H	
2650	ILLICIUM VERUM	A, H	When the plant preparation is oil or distillate, the nominal capacity of the container must

			be no more than 50 millilitres. When the concentration of Illicium verum oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
2651	IMIDUREA	E	Only for use in topical medicines for dermal application.
2652	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%.
2653	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%.
2654	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%.
2655	IMPATIENS BALSAMINA	A, H	
2656	IMPATIENS GLANDULIFERA	A, H	
2657	IMPERATA CYLINDRICA	A, E, H	
2658	INDIGO CARMINE	E	Permitted for use only as a colour for oral and topical use.
2659	INDIGO CARMINE ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
2660	INDIGOFERA TINCTORIA	A, H	
2661	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%.
2662	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.
2663	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%.
2664	INDUSTRIAL METHYLATED SPIRIT	E	
2665	INOSITOL	A, E	
2666	INULA BRITANNICA	A, H	
2667	INULA HELENIUM	A, E, H	
2668	INULA RACEMOSA	A, H	
2669	INULIN	A, E	
2670	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%.
2671	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).
2672	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, 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).
2673	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.
2674	IODOPROPYNYL BUTYLCARBAMATE	E	For use as an excipient ingredient in topical medicines only. The concentration in aqueous medicines must be no more than 10%.
2675	IONONE	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient

			formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
2676	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%.
2677	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%.
2678	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%.
2679	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%.

2680	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%.
2681	IPOMOEA BATATAS	A, H	
2682	IPOMOEA JALAPA	A, H	
2683	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.
2684	IRIS DOMESTICA	A, H	
2685	IRIS FLORENTINA	A, H	
2686	IRIS GERMANICA	A, H	
2687	IRIS PALLIDA	A, H	
2688	IRIS TENAX	H	
2689	IRIS VERSICOLOR	A, H	
2690	IRON	A, H	Only for use in oral medicines. When used as an active ingredient, the medicine must contain a daily dose of no more

		than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no 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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency

			conditions' (or words to that effect). 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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2691	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 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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). 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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).

2692	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 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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label:

			- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). 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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2693	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 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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). 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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label

			if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2694	IRON AMINO ACID CHELATE	A, H	Only for use in oral medicines. When used internally, iron is a mandatory component of iron amino acid chelate. The concentration of iron in iron amino acid chelate must be no more than 25%. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. 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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). 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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).

2695	IRON OXIDE BLACK	E	Permitted for use only as a colour for oral and topical use. 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.
2696	IRON OXIDE RED	E	Permitted for use only as a colour for oral and topical use. 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.
2697	IRON OXIDE YELLOW	E	Permitted for use only as a colour for oral and topical use. 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.
2698	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 specific iron-deficiency related claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect). 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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2699	IRONE	E	
2700	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%.

2701	ISATIS TINCTORIA	A, H	
2702	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%.
2703	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%.
2704	ISOAMYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2705	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%.
2706	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%.
2707	ISOAMYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2708	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%.
2709	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%.
2710	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%.
2711	ISOAMYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2712	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%.
2713	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%.
2714	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%.
2715	ISOAMYL LAURATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 12%.
2716	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 be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine

			label if supplied after 1 July 2019: - (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).
2717	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%.
2718	ISOAMYL PHENYLETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
2719	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%.
2720	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%.
2721	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%.
2722	ISOBORNEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

			fragrance concentration in a medicine must be no more 1%.
2723	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%.
2724	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%.
2725	ISOBUTANE	E	Only for use in topical medicines for dermal application.
2726	ISOBUTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

			fragrance concentration in a medicine must be no more 1%.
2727	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.
2728	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%.
2729	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%.
2730	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%.

2731	ISOBUTYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2732	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%.
2733	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%.
2734	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.
2735	ISOBUTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2736	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%.
2737	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%.
2738	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%.
2739	ISOBUTYL QUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2740	ISOBUTYL SALICYLATE	E	Only for use in topical medicines for dermal application.
2741	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.
2742	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%.
2743	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%.
2744	ISOCETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2745	ISOCETYL LINOLEOYL STEARATE	E	Only for use in topical medicines for dermal application.
2746	ISOCETYL STEARATE	E	Only for use in topical medicines for dermal application.
2747	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%.

2748	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%.
2749	ISODECYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
2750	ISODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2751	ISODECYL OLEATE	E	Only for use in topical medicines for dermal application.
2752	ISODECYL SALICYLATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 2%.
2753	ISODODECANE	E	Only for use in topical medicines for dermal application.
2754	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%.
2755	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%.
2756	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%.
2757	ISOEUGENYL BENZYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

2758	ISOHEXADECANE	E	Only for use in topical medicines for dermal application.
2759	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%.
2760	ISOLEUCINE	A, E	
2761	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]'.

2762	ISOMENTHONE	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%.
2763	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%.
2764	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%.
2765	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%.

2766	ISOPENTANE	E	For dental use only. The concentration must be no more than 2%.
2767	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%.
2768	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%.
2769	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%.
2770	ISOPROPYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2771	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.
2772	ISOPROPYL ACETATE	E	Only for use in topical medicines for dermal application.
2773	ISOPROPYL ALCOHOL	E	

2774	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%.
2775	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%.
2776	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
2777	ISOPROPYL LANOLATE	E	Only for use in topical medicines for dermal application.
2778	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%.
2779	ISOPROPYL MYRISTATE	E	

2780	ISOPROPYL PALMITATE	E	Only for use in topical medicines for dermal application.
2781	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%.
2782	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2783	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%.
2784	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%.
2785	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%.
2786	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%.
2787	ISOSTEARIC ACID	E	Only for use in topical medicines for dermal application.
2788	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%.
2789	ISOSTEARYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2790	ISOSTEARYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.

2791	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%.
2792	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%.
2793	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%.
2794	ISOVALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2795	ISPAGHULA HUSK DRY	A, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
2796	ISPAGHULA HUSK POWDER	A, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
2797	IVA AXILLARIS	A, H	
2798	JAMAICA DOGWOOD BARK DRY	A, H	
2799	JAMAICA DOGWOOD BARK POWDER	A, H	
2800	JASMINE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

			medicine must be no more 1%.
2801	JASMINE LACTONE	E	Only for use in topical medicines for dermal application.
2802	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%.
2803	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%.
2804	JASMINUM OFFICINALE	A, E, H	
2805	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%.
2806	JATEORHIZA PALMATA	A, H	

2807	JATROPHA CURCAS	H	Only for use as an active homoeopathic ingredient
2808	JERUSALEM ARTICHOKE	E	
2809	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%.
2810	JUGLANS CINEREA	A, E, H	
2811	JUGLANS NIGRA	A, E, H	
2812	JUGLANS REGIA	A, H	
2813	JUNCUS EFFUSUS	A, H	
2814	JUNIPER BERRY OIL	A, E, H	
2815	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%.
2816	JUNIPERUS CALIFORNICA	A, H	
2817	JUNIPERUS COMMUNIS	A, E, H	
2818	JUNIPERUS MEXICANA	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	JUNIPERUS OXYCEDRUS	A, H	
2820	JUNIPERUS VIRGINIANA	A, E, H	
2821	JUSTICIA ADHATODA	A, H	