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**
2173	FABIANA IMBRICATA	A, H	
2174	FAGOPYRUM ESCULENTUM	A, H	
2175	FAGUS GRANDIFOLIA	A, H	
2176	FAGUS SYLVATICA	A, H	
2177	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%.
2178	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%.
2179	FAST GREEN FCF	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2180	FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2181	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%.
2182	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%.
2183	FENNEL BITTER SEED DRY	A, E, H	When used in oral medicines, the following warning statements are required on the label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.'
2184	FENNEL LEAF	E	
2185	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

Authorised Version F2024L00649 registered 06/06/2024

			the container, and the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children (or words to that effect).' The maximum daily dose must provide no more than 150 mg of fennel oil. When used in oral medicines, the following warning statements are required on the label: - (CHILD3) ‘Use in children under 12 years is not recommended.’ - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect).' - (BREASF) 'Do not use while breastfeeding.'
2186	FENNEL SWEET SEED DRY	A, E, H	When used in oral medicines, the following warning statements are required on the label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.'
2187	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%.
2188	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2189	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, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2190	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

Authorised Version F2024L00649 registered 06/06/2024

			(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).
2191	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

Authorised Version F2024L00649 registered 06/06/2024

			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).
2192	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

Authorised Version F2024L00649 registered 06/06/2024

			are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2193	FERRIC OXIDE	E	
2194	FERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2195	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.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			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).
2196	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.
2197	FERROSOFERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2198	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

Authorised Version F2024L00649 registered 06/06/2024

			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).
2199	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

Authorised Version F2024L00649 registered 06/06/2024

			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).
2200	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.

Authorised Version F2024L00649 registered 06/06/2024

			When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2201	FERROUS IODIDE	H	Only for use as an active homoeopathic ingredient.
2202	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

Authorised Version F2024L00649 registered 06/06/2024

			support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2203	FERROUS 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).

Authorised Version F2024L00649 registered 06/06/2024

2204	FERROUS PICRATE	H	Only for use as an active homoeopathic ingredient.
2205	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).
2206	FERROUS SULFATE HEPTAHYDRATE	A, E, H	When for internal use, iron is a mandatory component of ferrous sulfate heptahydrate.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			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).
2207	FERULA ASSA-FOETIDA	A, E, H	
2208	FERULA FOETIDA	A, E, H	
2209	FERULA GALBANIFLUA	A, E, H	
2210	FERULA RUBRICAULIS	A, E, H	
2211	FERULA SUMBUL	A, H	
2212	FERULIC ACID	E	Only for use in topical medicines for dermal application.
2213	FESTUCA ELATIOR	A, H	

Authorised Version F2024L00649 registered 06/06/2024

2214	FEVERFEW HERB DRY	A, H	
2215	FEVERFEW HERB POWDER	A, H	
2216	FICUS CARICA	A, E, H	
2217	FICUS PUMILA	A, H	
2218	FIG	E	
2219	FIG DRY	A, H	
2220	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. The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25%; ii) the following warning statements are required on the medicine label:

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
2221	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%.
2222	FIR NEEDLE OIL CANADIAN	A, E	
2223	FIR NEEDLE OIL SIBERIAN	A, E	
2224	FIRMIANA SIMPLEX	A, E, H	
2225	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2226	FLEMINGIA MACROPHYLLA	A, H	
2227	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%.
2228	FLUORESCEIN SODIUM	E	

Authorised Version F2024L00649 registered 06/06/2024

2229	FOENICULUM VULGARE	A, E, H	When used in oral medicines, the following warning statements are required on the label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.' When the plant preparation is oil or distillate, methyl chavicol is a mandatory component and the maximum daily dose must provide no more than 150 mg of the plant preparation. When the plant preparation is oil or distillate and the concentration of methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL, a restricted flow insert must be fitted on the container, and the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
2230	FOLIC ACID	A	When for internal use, the maximum recommended daily dose must not provide more than 500 micrograms of folic acid. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.
2231	FOOD ORANGE 6	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2232	FOOD ORANGE 7	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2233	FOOD RED 13	E	Permitted for use only as a colour for topical use.
2234	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%.
2235	FORMIC ACID	E, H	Formic acid must only be included in medicines: (a) as an active homoeopathic ingredient; or (b) when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing formic acid must not be more than 5% of the total medicine. The maximum recommended daily dose of the medicine must not provide more than 150 mg of formic acid. The total concentration of formic acid in the medicine must not be more than 0.5%.
2236	FORSYTHIA SUSPENSA	A, H	
2237	FORTIFIED WINE	E	Ethanol is a mandatory component of fortified wine.
2238	FRACTIONATED COCONUT OIL	E	
2239	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.

Authorised Version F2024L00649 registered 06/06/2024

2240	FRAGARIA CHILOENSIS	A, E, H	
2241	FRAGARIA VESCA	A, E, H	
2242	FRAGARIA VIRGINIANA	A, E, H	
2243	FRAGARIA X ANANASSA	A, E, H	
2244	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

Authorised Version F2024L00649 registered 06/06/2024

			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'.
2245	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'.

Authorised Version F2024L00649 registered 06/06/2024

			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'.
2246	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

Authorised Version F2024L00649 registered 06/06/2024

			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'.
2247	FRAXINUS AMERICANA	A, H	
2248	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A, H	
2249	FRAXINUS EXCELSIOR	A, H	
2250	FRAXINUS ORNUS	A, H	
2251	FRITILLARIA CIRRHOSA	A, H	
2252	FRITILLARIA THUNBERGII	A, H	
2253	FRITILLARIA VERTICILLATA	A, H	
2254	FRUCTOOLIGOSACCHARIDES	A, E	
2255	FRUCTOSE	A, E, H	
2256	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.

Authorised Version F2024L00649 registered 06/06/2024

2257	FULLY HYDROGENATED RAPESEED OIL	E	Fully hydrogenated rapeseed oil must only be used in topical medicines for dermal application. The total concentration of fully hydrogenated rapeseed oil in the medicine must not be more than 5%.
2258	FUMARIA OFFICINALIS	A, E, H	
2259	FUMARIC ACID	E, H	Only for use as an active homoeopathic or excipient ingredient.
2260	FUMITORY HERB DRY	A, H	
2261	FUMITORY HERB POWDER	A, H	
2262	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%.
2263	FURFURAL	E	Permitted for use only in medicines containing 0.1% or less of furfural and in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must not be more than 5%. If used in a fragrance the total fragrance concentration in a medicine must not be more than 1%.
2264	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%.
2265	FURFURYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2266	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%.
2267	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%.
2268	GALACTOOLIGOSACCHARIDES	A	Only to be used in a medicine where FrieslandCampina Ingredients B V (Client ID 79530), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 May 2025. Lactose and glucose are mandatory components of galactooligosaccharides. The route of administration for medicines that contain galactooligosaccharides must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than: (a) 8 g of galactooligosaccharides to individuals aged 0 to 3 years (inclusive); and (b) 16.2 g of galactooligosaccharides to individuals aged 4 years and older.

Authorised Version F2024L00649 registered 06/06/2024

			The following warning statement (or words to the same effect) is required on the medicine label: (GOS) 'Not to be taken on the same day with other products containing galactooligosaccharides.'
2269	GALBANUM OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2270	GALBANUM 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%.
2271	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%.
2272	GALEGA OFFICINALIS	A, H	
2273	GALEOPSIS SEGETUM	A, H	
2274	GALIUM APARINE	A, H	
2275	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2276	GALIUM PALUSTRE	A, H	
2277	GALIUM VERUM	A, H	
2278	GALL STONE	H	Only for use as an active homoeopathic ingredient.
2279	GALPHIMIA GLAUCA	A, H	
2280	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%.
2281	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%.
2282	GAMMA-CYCLODEXTRIN	E	
2283	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%.
2284	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%.

Authorised Version F2024L00649 registered 06/06/2024

2285	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%.
2286	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%.
2287	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%.
2288	GAMMA-LINOLEIC ACID	E	Only for use in topical medicines for dermal application.
2289	GAMMA-LINOLENIC ACID	E	
2290	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2291	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%.
2292	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%.
2293	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%.
2294	GAMMA-TOCOPHEROL	E	
2295	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%.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2296	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%.
2297	GANODERMA LUCIDUM	A, E, H	
2298	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.
2299	GARCINIA QUAESITA	A, H	
2300	GARDEN BEAN	E	
2301	GARDENIA JASMINOIDES	A, E	
2302	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%
2303	GARLIC BULB DRY	A, E, H	
2304	GARLIC BULB FRESH	A, H	
2305	GARLIC BULB POWDER	A, E, H	
2306	GARLIC CLOVE POWDER	A, H	
2307	GARLIC OIL	A, E, H	
2308	GASTRODIA ELATA	A, H	
2309	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.

Authorised Version F2024L00649 registered 06/06/2024

	When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application i) the concentration of methyl salicylate in the medicine must not be more than 25%; ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);

Authorised Version F2024L00649 registered 06/06/2024

			iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
2310	GELATIN	A, E	
2311	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.
2312	GELLAN GUM	E	
2313	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%.
2314	GELSEMIUM POWDER	A, H	
2315	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%.
2316	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%.
2317	GENTIAN DRY	A, H	
2318	GENTIAN POWDER	A, H	

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2319	GENTIANA LUTEA	A, E, H	
2320	GENTIANA MACROPHYLLA	A, H	
2321	GENTIANA RHODANTHA	A, H	
2322	GENTIANA SCABRA	A, H	
2323	GENTIANELLA AMARELLA	A, H	
2324	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%.
2325	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%.
2326	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%.
2327	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%.
2328	GERANIUM MACULATUM	A, E, H	
2329	GERANIUM OIL	A, E, H	
2330	GERANIUM OIL SAPONIFIED	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2331	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%.
2332	GERANIUM ROBERTIANUM	A, E, H	
2333	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%.
2334	GERANIUM SIBIRICUM	A, E, H	
2335	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%.
2336	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%.
2337	GERANYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2338	GERANYL 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%.
2339	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%.
2340	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%.
2341	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%.

Authorised Version F2024L00649 registered 06/06/2024

2342	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%.
2343	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%.
2344	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%.
2345	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%.
2346	GEUM RIVALE	A, H	
2347	GEUM URBANUM	A, H	
2348	GHATTI GUM	A, E, H	
2349	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.

Authorised Version F2024L00649 registered 06/06/2024

			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2350	GINGER DRY	A, E, H	
2351	GINGER OIL	A, E, H	
2352	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%.
2353	GINGER POWDER	A, E, H	
2354	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.
2355	GLACIAL ACETIC ACID	E, H	The concentration in the medicine must be no more than 1.5%.
2356	GLECHOMA HEDERACEA	A, H	
2357	GLECHOMA LONGITUBA	A, H	
2358	GLEDITSIA AUSTRALIS	A, H	
2359	GLEDITSIA SINENSIS	A, H	
2360	GLEHNIA LITTORALIS	A, H	
2361	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%.

Authorised Version F2024L00649 registered 06/06/2024

2362	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2363	GLUCONOLACTONE	E	
2364	GLUCOSAMINE HYDROCHLORIDE	A, E	
2365	GLUCOSAMINE SULFATE	A	
2366	GLUCOSAMINE SULFATE POTASSIUM CHLORIDE	A	Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride. When for oral use, the medicine requires the following warning statement on the medicine label: - (POTAS1) 'If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'
2367	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	
2368	GLUCOSE	A, E, H	
2369	GLUCOSE GLUTAMATE	E	Only for use in topical medicines for dermal application.
2370	GLUCOSE MONOHYDRATE	A, E, H	
2371	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%.
2372	GLUTAMIC ACID	A, E	Only for use in topical medicines for dermal application.
2373	GLUTAMIC ACID HYDROCHLORIDE	A, E, H	
2374	GLUTAMINE	A, E, H	
2375	GLUTARAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2376	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).
2377	GLUTEN-FREE WHEAT STARCH	E	
2378	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%.
2379	GLYCEROL	A, E	When used as an active ingredient, it is only for use in topical medicines for dermal application.
2380	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.

Authorised Version F2024L00649 registered 06/06/2024

2381	GLYCEROL ESTER OF PARTIALLY HYDROGENATED WOOD ROSIN	E	Glycerol ester of partially hydrogenated wood rosin must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application.
2382	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%.
2383	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%.
2384	GLYCERYL DIISOSTEARATE	E	For use in topical medicines for dermal application.
2385	GLYCERYL DILAURATE	E	Only for use in topical medicines for dermal application.
2386	GLYCERYL DIOLEATE	E	Only for use in topical medicines for dermal application.
2387	GLYCERYL DISTEARATE	E	Only for use in topical medicines for dermal application.
2388	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2389	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%.
2390	GLYCERYL LAURATE	E	Only for use in topical medicines for dermal application.
2391	GLYCERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2392	GLYCERYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2393	GLYCERYL MONO AND DICAPRYLOCAPRATE	E	Only permitted for use in medicines limited to oral routes of administration, or when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The maximum recommended oral daily dose of the medicine must not provide more than 8 mg of glyceryl mono and dicaprylocaprate. The total concentration of fragrance proprietary excipient formulations containing glyceryl mono and dicaprylocaprate must not be more than 1% of the total medicine.
2394	GLYCERYL MONOOLEATE	E	
2395	GLYCERYL MONOSTEARATE	E	
2396	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2397	GLYCERYL OLEATE CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4% of the formulation.

Authorised Version F2024L00649 registered 06/06/2024

2398	GLYCERYL PALMITO-STEARATE	E	
2399	GLYCERYL POLYACRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.
2400	GLYCERYL POLYMETHACRYLATE	E	Only for use in topical medicines for dermal application.
2401	GLYCERYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2402	GLYCERYL ROSINATE	E	Only for use when the dosage form is 'chewing gum'. Must comply with: a) the Glycerol Ester of Gum Rosin monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia National Formulary, as in force or existing from time to time.
2403	GLYCERYL SORBITAN OLEOSTEARATE	E	Only for use in topical medicines for dermal application.
2404	GLYCERYL STARCH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 4%. The residual levels of epichlorohydrin are to be kept below the level of detection.
2405	GLYCERYL STEARATE CITRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2406	GLYCERYL TRIACETYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 6%.
2407	GLYCERYL TRIACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2408	GLYCERYL TRINITRATE	H	Only for use as an active homoeopathic ingredient. The total concentration of glyceryl trinitrate in the medicine must not be more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
2409	GLYCERYL UNDECYLENATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration of glyceryl undecylenate in a medicine must be no more than 3%.
2410	GLYCINE	A, E	
2411	GLYCINE MAX	A, E, H	
2412	GLYCOGEN	E	Only for use in topical medicines for dermal application.
2413	GLYCOL DISTEARATE	E	Only for use in topical medicines for dermal application.
2414	GLYCOLIC ACID	E	Only for use in topical medicines for dermal application. Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose. When present as an excipient in sunscreens, the concentration in the medicine must be no more than 5%.

Authorised Version F2024L00649 registered 06/06/2024

			When used as an excipient ingredient in other medicines the concentration in the medicine must be no more than 20%. If the concentration is more than 5% but no more than 20%, the pH of the medicine must be 3.5 or greater.
2415	GLYCYRRHIZA GLABRA	A, E, H	
2416	GLYCYRRHIZA SPECIES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2417	GLYCYRRHIZA URALENSIS	A, E, H	
2418	GLYCYRRHIZINIC ACID	E	
2419	GNAPHALIUM AFFINE	A, H	
2420	GNAPHALIUM POLYCEPHALUM	A, H	
2421	GNAPHALIUM ULIGINOSUM	A, H	
2422	GOAT	H	Only for use as an active homoeopathic ingredient.
2423	GOAT MILK	E	
2424	GOLD	E, H	Only for use as an active homoeopathic or excipient ingredient.
2425	GOLD CHLORIDE	H	Only for use as an active homoeopathic ingredient.
2426	GOLDEN ROD HERB DRY	A, E, H	
2427	GOLDEN SEAL ROOT DRY	A, H	
2428	GOLDEN SEAL ROOT POWDER	A, H	
2429	GOLDEN SYRUP	E	When the route of administration of the medicine is oral or sublingual, sucrose is a mandatory component of golden syrup.
2430	GOMPHRENA GLOBOSA	A, H	
2431	GOSSYPIUM HERBACEUM	A, E, H	
2432	GRAPE	E	

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2433	GRAPE SEED OIL	E	
2434	GRAPE WINE RED	E	Ethanol is a mandatory component of grape wine red.
2435	GRAPE WINE SHERRY	E	Ethanol is a mandatory component of grape wine sherry.
2436	GRAPE WINE WHITE	E	Ethanol is a mandatory component of grape wine white.
2437	GRAPEFRUIT	E	
2438	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%.
2439	GRAPEFRUIT OIL COLDPRESSED	A, E, H	
2440	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%.
2441	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%.
2442	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%.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2443	GRAPHITE	H	Only for use as an active homoeopathic ingredient.
2444	GRATIOLA LINIFOLIA	A, H	
2445	GREATER NETTLE HERB DRY	A, H	
2446	GREATER NETTLE HERB POWDER	A, H	
2447	GREATER NETTLE ROOT DRY	A, H	
2448	GREATER NETTLE ROOT POWDER	A, H	
2449	GREEN LIPPED MUSSEL	A	The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
2450	GREEN LIPPED MUSSEL DRIED	A	The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
2451	GREEN LIPPED MUSSEL OIL	A	The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
2452	GREEN S	E	Only for use as a colour in topical and oral medicines.
2453	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.'
2454	GRINDELIA CAMPORUM	A, H	
2455	GRINDELIA ROBUSTA	A, H	

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2456	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%.
2457	GROUND IVY HERB DRY	A, H	
2458	GROUND IVY HERB POWDER	A, H	
2459	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%.
2460	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%.
2461	GUAIACUM OFFICINALE	A, E, H	
2462	GUAIACUM RESIN	A, E, H	
2463	GUAIACUM SANCTUM	A, H	
2464	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%.
2465	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%.

Authorised Version F2024L00649 registered 06/06/2024

2466	GUANINE	E	Only for use as an excipient in topical medicines for dermal application.
2467	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.
2468	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).
2469	GUAR GUM	A, E, H	
2470	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	E	Only for use as an excipient in topical medicines for dermal application.
2471	GUAREA RUSBYI	A, H	
2472	GUAVA	E	
2473	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%.
2474	GYMNADENIA NIGRA	A	

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2475	GYMNEMA SYLVESTRE	A, H	
2476	GYMNOCLADUS DIOICA	A, H	
2477	GYNOSTEMMA PENTAPHYLLUM	A	The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).
2478	HAHNEMANN'S SOLUBLE MERCURY	H	Only for use as an active homoeopathic ingredient.
2479	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

Authorised Version F2024L00649 registered 06/06/2024

			women and 900 micrograms retinol equivalents for men.’
2480	HAMAMELIS LEAF DRY	A, H	
2481	HAMAMELIS LEAF POWDER	A, H	
2482	HAMAMELIS VIRGINIANA	A, E, H	
2483	HAMAMELIS WATER	A, E, H	
2484	HANDROANTHUS HEPTAPHYLLUS	A, H	
2485	HANDROANTHUS IMPETIGINOSUS	A, E, H	
2486	HARD FAT	E	
2487	HARD PARAFFIN	E	
2488	HARICOT BEAN	E	
2489	HARPAGOPHYTUM PROCUMBENS	A, E, H	
2490	HARUNGANA MADAGASCARIENSIS	A, H	
2491	HAZEL NUT	E	
2492	HAZEL NUT OIL	E	
2493	HEAVY KAOLIN	E	
2494	HEAVY MAGNESIUM OXIDE	A, E, H	Magnesium is a mandatory component of heavy magnesium oxide. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label:

Authorised Version F2024L00649 registered 06/06/2024

			- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
2495	HECTORITE	E	Only for use in topical medicines for dermal application.
2496	HEDEOMA PULEGIOIDES	A	
2497	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%.
2498	HEDTA	E	Only for use as an excipient in topical medicines for dermal application.
2499	HEKLA LAVA	H	Only for use as an active homoeopathic ingredient.
2500	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%.
2501	HELIANTHEMUM NUMMULARIUM	A, H	
2502	HELIANTHUS ANNUUS	A, E, H	
2503	HELIANTHUS TUBEROSUS	A, H	
2504	HELICHRYSUM ANGUSTIFOLIUM	A, E, H	
2505	HELICHRYSUM ARENARIUM	A, H	
2506	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%.

Authorised Version F2024L00649 registered 06/06/2024

2507	HELLEBORUS NIGER	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2508	HELLEBORUS VIRIDIS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2509	HELONIAS RHIZOME DRY	A, H	
2510	HELONIAS RHIZOME POWDER	A, H	
2511	HEMIDESMUS INDICUS	A, E, H	
2512	HEMP SEED OIL	A, E	Only to be used in a medicine where Elixinol Wellness (Byron Bay) Pty Ltd (Client ID 78778), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 13 December 2024. Cannabidiol and tetrahydrocannabinols are mandatory components of hemp seed oil. The total concentration of cannabidiol in hemp seed oil must not be more than 75 mg/kg. The total concentration of tetrahydrocannabinols in hemp seed oil must not be more than 10 mg/kg. The route of administration for medicines that contain hemp seed oil must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 36 g of hemp seed oil. The following warning statements (or words to that effect) are required on the medicine label: - ‘Not for use in children under 2 years of age’; and

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			- 'Not to be taken on the same day with other products containing hemp seed oil, including food sources'.
2513	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%.
2514	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%.
2515	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%.
2516	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%.
2517	HEPTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2518	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%.
2519	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%.
2520	HERACLEUM HEMSLEYANUM	A, H	
2521	HERNIARIA GLABRA	A, H	
2522	HESPERIDIN	A, E	
2523	HESPEROCYPARIS MACROCARPA	A, H	
2524	HESPEROYUCCA WHIPPLEI	A, H	
2525	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%.
2526	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%.
2527	HEXAMETHYLINDANOPYRAN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2528	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%.
2529	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.
2530	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%.
2531	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%.

Authorised Version F2024L00649 registered 06/06/2024

2532	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 %.
2533	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%.
2534	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%.
2535	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%.
2536	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2537	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%.
2538	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%.
2539	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%.
2540	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%.
2541	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2542	HEXYL NICOTINATE	E	
2543	HEXYL PROPIONATE	E	Only for use in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
2544	HEXYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2545	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%.
2546	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%.
2547	HEXYLENE GLYCOL	E	Only for use as an excipient in topical medicines for dermal application.
2548	HEXYLRESORCINOL	A	Permitted for use only in medicated throat lozenges. The medicine of must not contain more than 2.5 mg of hexylresorcinol per lozenge. The maximum recommended daily dose of the medicine must not provide more than 30mg of hexylresorcinol. The medicine label must specify that the medicine is only to be used for 7 days (or less). The following warning statement must be included on the medicine label: - (PREGNT) ‘Not recommended for use by pregnant and lactating women’ (or words to that effect).
2549	HIBISCUS ESCULENTUS	A, H	
2550	HIBISCUS MUTABILIS	A, H	

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2551	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%.
2552	HIBISCUS SABDARIFFA	A, E, H	
2553	HIERACIUM PILOSELLA	A, H	
2554	HIGH AMYLOSE MAIZE STARCH	A, E, H	
2555	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.
2556	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%.
2557	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.
2558	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:

Authorised Version F2024L00649 registered 06/06/2024

			- (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.'
2559	HIMATANTHUS LANCIFOLIUS	A, E, H	
2560	HIPPOPHAE RHAMNOIDES	A, E, H	
2561	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%.
2562	HISTAMINE DIHYDROCHLORIDE	H	Only for use as an active homoeopathic ingredient.
2563	HISTIDINE	A	
2564	HISTIDINE HYDROCHLORIDE	A, E, H	
2565	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%.
2566	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%.
2567	HOLCUS LANATUS	A, H	

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2568	HOLY THISTLE HERB DRY	A, H	
2569	HOLY THISTLE HERB POWDER	A, H	
2570	HOMALOMENA OCCULTA	A, H	
2571	HOMOSALATE	A, E	For use as an active ingredient only in sunscreens for dermal application. For use as an excipient only in topical medicines for dermal application. Not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 15%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2572	HONEY	A, E	When the route of administration is oral, the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).
2573	HONEY BEE	H	Only for use as an active homoeopathic ingredient.
2574	HONEY EXTRACT	E	Honey extract must not be included in medicines intended for use in the eye. The concentration of honey extract in the medicine must not be more than 1%.
2575	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%.

Authorised Version F2024L00649 registered 06/06/2024

2576	HOP STROBILE DRY	A, H	
2577	HOP STROBILE POWDER	A, H	
2578	HOPS OIL	A, E, H	
2579	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.
2580	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.
2581	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%.
2582	HOTTONIA PALUSTRIS	A, H	
2583	HOUTTUYNIA CORDATA	A, H	
2584	HOVENIA DULCIS	A, H	
2585	HUMULUS LUPULUS	A, E, H	
2586	HYALURONIC ACID	E	Only for use as an excipient in topical medicines for dermal application.
2587	HYDNOCARPUS CASTANEUS	A, H	When the medicine is for other than topical use and the plant part is seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry seed.
2588	HYDRANGEA ARBORESCENS	A, H	
2589	HYDRANGEA PANICULATA	A, H	
2590	HYDRASTIS CANADENSIS	A, E, H	
2591	HYDRATED SILICA	E	Only for use when the route of administration is other than inhalation.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2592	HYDROCHLORIC ACID	E	The concentration of the medicine must be no more than 0.5%.
2593	HYDROCOTYLE UMBELLATA	A, H	
2594	HYDROGEN CYANIDE	H	Only for use as an active homoeopathic ingredient.
2595	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.
2596	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%.
2597	HYDROGENATED C6-14 OLEFIN POLYMERS	E	Only permitted for use in solid or semi-solid medicines for dermal application or in topical medicines for dermal application: (a) containing 25% or less of hydrocarbons, liquid; or (b) when packed in pressurised spray packs; or (c) when packed in containers with a capacity of 2 millilitres or less. Not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 7%.

Authorised Version F2024L00649 registered 06/06/2024

2598	HYDROGENATED CASTOR OIL	E	
2599	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%.
2600	HYDROGENATED COCONUT OIL	E	
2601	HYDROGENATED COTTONSEED OIL	E	
2602	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.
2603	HYDROGENATED ETHYLENE/PROPYLENE/STYRENE COPOLYMER	E	The combined concentration of hydrogenated ethylene/propylene/styrene copolymer must be no more than 9%.
2604	HYDROGENATED LANOLIN	E	
2605	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%.
2606	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%.
2607	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2608	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%.
2609	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.
2610	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.
2611	HYDROGENATED POLYDEXTROSE	A	Only permitted for use in medicines: (a) limited to oral routes of administration; and (b) when the maximum recommended daily dose does not provide more than 15 g of hydrogenated polydextrose.
2612	HYDROGENATED POLYISOBUTENE	E	Only for use in topical medicines for dermal application.
2613	HYDROGENATED SOYA OIL	E	
2614	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%.
2615	HYDROGENATED VEGETABLE OIL	E	
2616	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%.

Authorised Version F2024L00649 registered 06/06/2024

2617	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%
2618	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%
2619	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%.
2620	HYDROLYSED CHICKEN CARTILAGE EXTRACT	A	The route of administration for medicines that contain hydrolysed chicken cartilage extract must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 2000 mg hydrolysed chicken cartilage extract. The following warning statement (or words to the same effect) is required on the medicine label: - (ADULT) 'Adults only’.
2621	HYDROLYSED COLLAGEN	A, E	
2622	HYDROLYSED ELASTIN	E	Only for use in topical medicines for dermal application.
2623	HYDROLYSED GELATIN	A, E	
2624	HYDROLYSED GLYCOSAMINOGLYCANS	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2625	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%.
2626	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%.
2627	HYDROLYSED MAIZE STARCH	E	
2628	HYDROLYSED MILK PROTEIN	E	
2629	HYDROLYSED RICE	A, E, H	
2630	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%.
2631	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%.
2632	HYDROLYSED VEGETABLE PROTEIN	E	
2633	HYDROLYSED WHEAT PROTEIN	E	Gluten is a mandatory component of hydrolysed wheat protein.
2634	HYDROLYSED WHEAT PROTEIN/PVP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.2%.

Authorised Version F2024L00649 registered 06/06/2024

2635	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%.
2636	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%.
2637	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.
2638	HYDROXOCOBALAMIN	A	
2639	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%.
2640	HYDROXYAPATITE	A, E	
2641	HYDROXYCITRATE COMPLEX	A	Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.
2642	HYDROXYCITRIC ACID	A	

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2643	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%.
2644	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%.
2645	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%.
2646	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%.
2647	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%.

Authorised Version F2024L00649 registered 06/06/2024

2648	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%.
2649	HYDROXYLATED LANOLIN	E	
2650	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%.
2651	HYDROXYLYSINE	A, E	
2652	HYDROXYMETHYLCELLULOSE	E	
2653	HYDROXYOCTACOSANYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
2654	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%.
2655	HYDROXYPROLINE	A, E	
2656	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

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

			contain more than 240mg of hydroxypropyl distarch phosphate.
2657	HYDROXYPROPYL STARCH	E	
2658	HYDROXYPROPYLBETADEX	E	Only for use in topical medicines for dermal application.
2659	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%.
2660	HYETELLOSE	E	
2661	HYLOCEREUS LEMAIREI	E	Permitted for use only as a colour for oral and topical use.
2662	HYLOCEREUS UNDATUS	A, H	
2663	HYMETELLOSE	E	
2664	HYOSCYAMUS LEAF DRY	A, H	Alkaloids calculated as hyoscyamine and hyoscine are mandatory components of Hyoscamus leaf dry. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of hyoscine in the medicine must be no more than than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2665	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%.

Authorised Version F2024L00649 registered 06/06/2024

2666	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%.
2667	HYPERICUM ASCYRON	A, H	
2668	HYPERICUM JAPONICUM	A, H	
2669	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.'
2670	HYPROLOSE	E	
2671	HYPROMELLOSE	E	
2672	HYPROMELLOSE PHTHALATE	E	
2673	HYPTIS SUAVEOLENS	A, H	
2674	HYSSOPUS OFFICINALIS	A, E, H	
2675	IBERIS AMARA	A, H	
2676	ICHTHAMMOL	H	Only for use as an active homoeopathic ingredient.
2677	ILEX AQUIFOLIUM	A, H	
2678	ILEX CHINENSIS	A, H	
2679	ILEX PARAGUARIENSIS	A, E, H	Caffeine is a mandatory component of Ilex paraguariensis. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.

Authorised Version F2024L00649 registered 06/06/2024

	When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking

Authorised Version F2024L00649 registered 06/06/2024

			with other medicines' (or words to that effect).
2680	ILEX ROTUNDA	A, H	
2681	ILEX VERTICILLATA	A, H	
2682	ILLICIUM VERUM	A, H	When the plant preparation is oil or distillate, and the concentration of Illicium verum oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 50 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
2683	IMIDUREA	E	Only for use in topical medicines for dermal application.
2684	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%.
2685	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%.
2686	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2687	IMPATIENS BALSAMINA	A, H	
2688	IMPATIENS GLANDULIFERA	A, H	
2689	IMPERATA CYLINDRICA	A, E, H	
2690	INDIGO CARMINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2691	INDIGO CARMINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2692	INDIGOFERA TINCTORIA	A, H	
2693	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%.
2694	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.
2695	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%.
2696	INDUSTRIAL METHYLATED SPIRIT	E	
2697	INOSITOL	A, E	
2698	INULA BRITANNICA	A, H	
2699	INULA HELENIUM	A, E, H	
2700	INULA RACEMOSA	A, H	
2701	INULIN	A, E	
2702	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.

Authorised Version F2024L00649 registered 06/06/2024

			The concentration in the medicine must be no more than 1.2%.
2703	INVERT SUGAR	E	
2704	INVERT SYRUP	E	When the route of administration is oral or sublingual, glucose is a mandatory component of Invert syrup.
2705	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.
2706	IODOPROPYNYL BUTYLCARBAMATE	E	For use as an excipient ingredient in topical medicines only. The concentration in aqueous medicines must be no more than 10%.
2707	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%.
2708	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2709	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%.
2710	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%.
2711	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%.
2712	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%.
2713	IPOMOEA BATATAS	A, H	
2714	IPOMOEA JALAPA	A, H	
2715	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.
2716	IRIS DOMESTICA	A, H	
2717	IRIS FLORENTINA	A, H	
2718	IRIS GERMANICA	A, H	
2719	IRIS PALLIDA	A, H	
2720	IRIS TENAX	H	
2721	IRIS VERSICOLOR	A, H	
2722	IRON	A, H	Only for use in oral medicines.

Authorised Version F2024L00649 registered 06/06/2024

			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 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2723	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

Authorised Version F2024L00649 registered 06/06/2024

			when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2724	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

Authorised Version F2024L00649 registered 06/06/2024

			iron in the total contents of the container are required to have a child resistant closure. When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2725	IRON (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-

Authorised Version F2024L00649 registered 06/06/2024

			deficiency related claims, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2726	IRON 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, the following warning statement is required on the label:

Authorised Version F2024L00649 registered 06/06/2024

			- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2727	IRON OXIDE BLACK	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content. When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.
2728	IRON OXIDE RED	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content. When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.
2729	IRON OXIDE YELLOW	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content. When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2730	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, the following warning statement is required on the label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2731	IRONE	E	
2732	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%.

Authorised Version F2024L00649 registered 06/06/2024

2733	ISATIS TINCTORIA	A, H	
2734	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%.
2735	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%.
2736	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%.
2737	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%.
2738	ISOAMYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2739	ISOAMYL 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%.
2740	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%.
2741	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%.
2742	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%.

Authorised Version F2024L00649 registered 06/06/2024

2743	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%.
2744	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%.
2745	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%.
2746	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%.
2747	ISOAMYL LAURATE	E	Only for use in topical medicines for dermal application and not to be included

Authorised Version F2024L00649 registered 06/06/2024

			in topical medicines intended for use in the eye. The concentration must be no more than 12%.
2748	ISOAMYL METHOXYCINNAMATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2749	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%.
2750	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%.
2751	ISOAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2752	ISOAMYL 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%.
2753	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%.
2754	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%.
2755	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2756	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%.
2757	ISOBUTANE	E	Only for use in topical medicines for dermal application.
2758	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%.
2759	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.
2760	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%.
2761	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%.

Authorised Version F2024L00649 registered 06/06/2024

2762	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%.
2763	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%.
2764	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%.
2765	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%.
2766	ISOBUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
2767	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2768	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%.
2769	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%.
2770	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%.
2771	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%.
2772	ISOBUTYL SALICYLATE	E	Only for use in topical medicines for dermal application.
2773	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.
2774	ISOBUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2775	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%.
2776	ISOCETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2777	ISOCETYL LINOLEOYL STEARATE	E	Only for use in topical medicines for dermal application.
2778	ISOCETYL STEARATE	E	Only for use in topical medicines for dermal application.
2779	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%.
2780	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%.
2781	ISODECYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
2782	ISODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2783	ISODECYL OLEATE	E	Only for use in topical medicines for dermal application.
2784	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%.
2785	ISODODECANE	E	Only for use in topical medicines for dermal application.
2786	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%.
2787	ISOEUGENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. When the medicine is for dermal use, the total concentration of isoeugenol in the medicine must not be more than 0.02%.
2788	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%.

Authorised Version F2024L00649 registered 06/06/2024

2789	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%.
2790	ISOHEXADECANE	E	Only for use in topical medicines for dermal application.
2791	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%.
2792	ISOLEUCINE	A, E	
2793	ISOMALT	E	
2794	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%.
2795	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2796	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%.
2797	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%.
2798	ISOPENTANE	E	For dental use only. The concentration must be no more than 2%.
2799	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%.
2800	ISOPHORONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. The total concentration of isophorone in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
2801	ISOPHYTOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2802	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%.
2803	ISOPROPYL 4-HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
2804	ISOPROPYL ACETATE	E	Only for use in topical medicines for dermal application.
2805	ISOPROPYL ALCOHOL	E	
2806	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%.
2807	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%.
2808	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2809	ISOPROPYL LANOLATE	E	Only for use in topical medicines for dermal application.
2810	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%.
2811	ISOPROPYL MYRISTATE	E	
2812	ISOPROPYL PALMITATE	E	Only for use in topical medicines for dermal application.
2813	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%.
2814	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2815	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%.
2816	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%.
2817	ISOPULEGOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

			If 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%.
2818	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%.
2819	ISOSTEARIC ACID	E	Only for use in topical medicines for dermal application.
2820	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%.
2821	ISOSTEARYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2822	ISOSTEARYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2823	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%.
2824	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2825	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%.
2826	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%.
2827	ISPAGHULA HUSK DRY	A, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
2828	ISPAGHULA HUSK POWDER	A, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
2829	IVA AXILLARIS	A, H	
2830	JAMAICA DOGWOOD BARK DRY	A, H	
2831	JAMAICA DOGWOOD BARK POWDER	A, H	
2832	JASMINE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L00649 registered 06/06/2024

			If 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%.
2833	JASMINE LACTONE	E	Only for use in topical medicines for dermal application.
2834	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%.
2835	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%.
2836	JASMINUM OFFICINALE	A, E, H	
2837	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%.
2838	JATEORHIZA PALMATA	A, H	
2839	JATROPHA CURCAS	H	Only for use as an active homoeopathic ingredient
2840	JERUSALEM ARTICHOKE	E	
2841	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%.

Authorised Version F2024L00649 registered 06/06/2024

Volume 3

2842	JUGLANS CINEREA	A, E, H	
2843	JUGLANS NIGRA	A, E, H	
2844	JUGLANS REGIA	A, H	
2845	JUNCUS EFFUSUS	A, H	
2846	JUNIPER BERRY OIL	A, E, H	
2847	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%.
2848	JUNIPERUS CALIFORNICA	A, H	
2849	JUNIPERUS COMMUNIS	A, E, H	
2850	JUNIPERUS DEPPEANA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2851	JUNIPERUS OXYCEDRUS	A, H	
2852	JUNIPERUS VIRGINIANA	A, E, H	
2853	JUSTICIA ADHATODA	A, H	

Authorised Version F2024L00649 registered 06/06/2024