

## 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
2169	FABIANA IMBRICATA	A, H	
2170	FAGOPYRUM ESCULENTUM	A, H	
2171	FAGUS GRANDIFOLIA	A, H	
2172	FAGUS SYLVATICA	A, H	
2173	FARNESOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2174	FARNESYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
2175	FAST GREEN FCF	E	<p>Permitted for use only as a colour in medicines limited to topical and oral routes of administration.</p>

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

Volume 3

2176	FENCHONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2177	FENCHYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2178	FENCHYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2179	FENNEL BITTER SEED DRY	A, E, H	<p>When used in oral medicines, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended'</li> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'</li> <li>- (BREASF) 'Do not use while breastfeeding.'</li> </ul>

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

Volume 3

2180	FENNEL LEAF	E	
2181	FENNEL OIL	A, E, H	<p>Methyl chavicol is a mandatory component of fennel oil.</p> <p>When the concentration of methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL, a restricted flow insert must be fitted on the container, and the following warning statement is required on the label:</p> <p>- (CHILD) 'Keep out of reach of children (or words to that effect).'</p> <p>The maximum daily dose must provide no more than 150 mg of fennel oil.</p> <p>When used in oral medicines, the following warning statements are required on the label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended.'</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect).'</p> <p>- (BREASF) 'Do not use while breastfeeding.'</p>
2182	FENNEL SWEET SEED DRY	A, E, H	<p>When used in oral medicines, the following warning statements are required on the label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended'</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'</p> <p>- (BREASF) 'Do not use while breastfeeding.'</p>
2183	FENUGREEK	E	Permitted for use only in combination with other permitted

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

Volume 3

---

			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2184	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%.
2185	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

---

			<p>child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2186	FERRIC CHLORIDE	A, E, H	<p>When for internal use, iron is a mandatory component of ferric chloride.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a</p>

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

Volume 3

			<p>child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2187	FERRIC CHLORIDE HEXAHYDRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferric chloride hexahydrate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a</p>

			<p>child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2188	FERRIC GLYCEROPHOSPHATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferric glycerophosphate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a</p>

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

Volume 3

			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).
2189	FERRIC OXIDE	E	
2190	FERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2191	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.



			<p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2192	FERROSOFERRIC OXIDE	E	<p>When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.</p>
2193	FERROSOFERRIC PHOSPHATE	H	<p>Only for use as an active homoeopathic ingredient.</p>
2194	FERROUS FUMARATE	A, H	<p>When for internal use, iron is a mandatory component of ferrous fumarate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack</p>

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

Volume 3

---

			<p>must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:          - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2195	FERROUS GLUCONATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferrous gluconate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack</p>

---

			<p>must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2196	FERROUS GLUCONATE DIHYDRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferrous gluconate dihydrate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack</p>

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

Volume 3

			<p>must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2197	FERROUS IODIDE	H	Only for use as an active homoeopathic ingredient.
2198	FERROUS LACTATE TRIHYDRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferrous lactate trihydrate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron</p>

			<p>per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2199	FERROUS PHOSPHATE OCTAHYDRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferrous phosphate octahydrate.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron</p>

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

Volume 3

			<p>per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label:          - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2200	FERROUS PICRATE	H	Only for use as an active homoeopathic ingredient.
2201	FERROUS SULFATE	A, E, H	<p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron</p>

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

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

Volume 3

			<p>per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2203	FERULA ASSA-FOETIDA	A, E, H	
2204	FERULA FOETIDA	A, E, H	
2205	FERULA GALBANIFLUA	A, E, H	
2206	FERULA RUBRICAULIS	A, E, H	
2207	FERULA SUMBUL	A, H	
2208	FERULIC ACID	E	Only for use in topical medicines for dermal application.



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

Volume 3

2209	FESTUCA ELATIOR	A, H	
2210	FEVERFEW HERB DRY	A, H	
2211	FEVERFEW HERB POWDER	A, H	
2212	FICUS CARICA	A, E, H	
2213	FICUS PUMILA	A, H	
2214	FIG	E	
2215	FIG DRY	A, H	
2216	FILIPENDULA ULMARIA	A, H	<p>Methyl salicylate is a mandatory component of Filipendula ulmaria.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>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:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</li> </ul>

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

Volume 3

			<p>When for use in topical medicines for dermal application:</p> <p>i) the concentration of methyl salicylate in the medicine must not be more than 25%;</p> <p>ii) the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</li> </ul> <p>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (IRRIT) 'If irritation develops, discontinue use'.</li> </ul>
2217	FIR BALSAM ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2218	FIR NEEDLE OIL CANADIAN	A, E	
2219	FIR NEEDLE OIL SIBERIAN	A, E	
2220	FIRMIANA SIMPLEX	A, E, H	
2221	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2222	FLEMINGIA MACROPHYLLA	A, H	
2223	FLOUVE OIL	E	Permitted for use only in

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

Volume 3

			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2224	FLUORESCEIN SODIUM	E	
2225	FOENICULUM VULGARE	A, E, H	<p>When used in oral medicines, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended'</li> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)'</li> <li>- (BREASF) 'Do not use while breastfeeding.'</li> </ul> <p>When the plant preparation is oil or distillate, methyl chavicol is a mandatory component and the maximum daily dose must provide no more than 150 mg of the plant preparation.</p> <p>When the plant preparation is oil or distillate and the concentration of methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL, a restricted flow insert must be fitted on the container, and the following warning statement is required on the label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect).</li> </ul>
2226	FOLIC ACID	A	When for internal use, the maximum recommended daily

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

Volume 3

				<p>dose must not provide more than 500 micrograms of folic acid.</p> <p>When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.</p>
2227	FOOD ORANGE 6	E		Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2228	FOOD ORANGE 7	E		Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2229	FOOD RED 13	E		Permitted for use only as a colour for topical use.
2230	FORMALDEHYDE/MELAMINE/TOSYLAMIDE COPOLYMER	E		<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 10%.</p>
2231	FORMIC ACID	E, H		<p>Formic acid must only be included in medicines:</p> <p>(a) as an active homoeopathic ingredient; or</p> <p>(b) when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing formic acid must not be more than 5% of the total medicine.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 150 mg of</p>

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

Volume 3

			formic acid. The total concentration of formic acid in the medicine must not be more than 0.5%.
2232	FORSYTHIA SUSPENS	A, H	
2233	FORTIFIED WINE	E	Ethanol is a mandatory component of fortified wine.
2234	FRACTIONATED COCONUT OIL	E	
2235	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.
2236	FRAGARIA CHILOENSIS	A, E, H	
2237	FRAGARIA VESCA	A, E, H	
2238	FRAGARIA VIRGINIANA	A, E, H	
2239	FRAGARIA X ANANASSA	A, E, H	
2240	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

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

Volume 3

pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].

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

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

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

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and

- (LAX4) 'This product may have laxative effect'.

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

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

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

- (LAX2) 'Prolonged use may cause serious bowel problems'.

2241

FRANGULA BARK POWDER

A, H

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

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

- (CHILD3) 'Use in children under 12 years is not recommended';
- (LAX2) 'Prolonged use may cause serious bowel problems';  
and
- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]'.  
When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:
- (LAX1) 'Drink plenty of water [or words to that effect]'.  
When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:
- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and
- (LAX4) 'This product may have laxative effect'.  
When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:
- (CHILD3) 'Use in children under 12 years is not recommended';
- (LAX1) 'Drink plenty of water [or words to that effect]'; and
- (LAX2) 'Prolonged use may cause serious bowel problems'.

2242

FRANGULA PURSHIANA

A, H

When for oral use,

Volume 3

---

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

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

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

- (LAX2) 'Prolonged use may cause serious bowel problems';

and

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

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

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

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

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and

- (LAX4) 'This product may have laxative effect'.

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

---



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

Volume 3

			<p>following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
2243	FRAXINUS AMERICANA	A, H	
2244	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A, H	
2245	FRAXINUS EXCELSIOR	A, H	
2246	FRAXINUS ORNUS	A, H	
2247	FRITILLARIA CIRRHOSA	A, H	
2248	FRITILLARIA THUNBERGII	A, H	
2249	FRITILLARIA VERTICILLATA	A, H	
2250	FRUCTOOLIGOSACCHARIDES	A, E	
2251	FRUCTOSE	A, E, H	
2252	FUCUS VESICULOSUS	A, E, H	<p>Iodine is a mandatory component of Fucus vesiculosus.</p> <p>Only for external use when the concentration of available iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
2253	FULLY HYDROGENATED RAPESEED OIL	E	<p>Fully hydrogenated rapeseed oil must only be used in topical medicines for dermal application.</p> <p>The total concentration of fully hydrogenated rapeseed oil in the medicine must not be more than 5%.</p>
2254	FUMARIA OFFICINALIS	A, E, H	
2255	FUMARIC ACID	E, H	Only for use as an active

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

Volume 3

			homoeopathic or excipient ingredient.
2256	FUMITORY HERB DRY	A, H	
2257	FUMITORY HERB POWDER	A, H	
2258	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%.
2259	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%.
2260	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%.
2261	FURFURYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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

Volume 3

2262	FURFURYL MERCAPTAN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2263	FUSEL OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2264	GALACTOOLIGOSACCHARIDES	A	<p>Only to be used in a medicine where FrieslandCampina Ingredients B V (Client ID 79530), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 May 2025.</p> <p>Lactose and glucose are mandatory components of galactooligosaccharides.</p> <p>The route of administration for medicines that contain galactooligosaccharides must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(a) 8 g of galactooligosaccharides to individuals aged 0 to 3 years (inclusive); and</p> <p>(b) 16.2 g of galactooligosaccharides to individuals aged 4 years and older.</p>

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

Volume 3

			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.'
2265	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%.
2266	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%.
2267	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%.
2268	GALEGA OFFICINALIS	A, H	
2269	GALEOPSIS SEGETUM	A, H	

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

Volume 3

2270	GALIUM APARINE	A, H	
2271	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%.
2272	GALIUM PALUSTRE	A, H	
2273	GALIUM VERUM	A, H	
2274	GALL STONE	H	Only for use as an active homoeopathic ingredient.
2275	GALPHIMIA GLAUCA	A, H	
2276	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%.
2277	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%.
2278	GAMMA-CYCLODEXTRIN	E	
2279	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%.

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

Volume 3

---

---

2280	GAMMA-DODECALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2281	GAMMA-HEPTALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2282	GAMMA-HEXALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2283	GAMMA-IONONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

---

---

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

Volume 3

			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2284	GAMMA-LINOLEIC ACID	E	Only for use in topical medicines for dermal application.
2285	GAMMA-LINOLENIC ACID	E	
2286	GAMMA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2287	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%.
2288	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

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

Volume 3

			medicine must be no more 1%.
2289	GAMMA-TERPINENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2290	GAMMA-TOCOPHEROL	E	
2291	GAMMA-UNDECALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2292	GAMMA-VALEROLACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2293	GANODERMA LUCIDUM	A, E, H	
2294	GARCINIA GUMMI-GUTTA	A	<p>Only for use in oral medicines.</p> <p>Must be obtained from the rind of the fruit only.</p> <p>Must not contain any directions for use for children or pregnant or lactating women.</p>



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

Volume 3

2295	GARCINIA QUAESITA	A, H	
2296	GARDEN BEAN	E	
2297	GARDENIA JASMINOIDES	A, E	
2298	GARDENIA TAHITENSIS FLOWER EXTRACT	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.002%</p>
2299	GARLIC BULB DRY	A, E, H	
2300	GARLIC BULB FRESH	A, H	
2301	GARLIC BULB POWDER	A, E, H	
2302	GARLIC CLOVE POWDER	A, H	
2303	GARLIC OIL	A, E, H	
2304	GASTRODIA ELATA	A, H	
2305	GAULTHERIA PROCUMBENS	A, E, H	<p>Methyl salicylate is a mandatory component of Gaultheria procumbens.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>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:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> </ul>

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

Volume 3

- direct suction through the delivery device results in delivery of no more than one dosage unit; and

- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

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

When for use in topical medicines for dermal application

i) the concentration of methyl salicylate in the medicine must not be more than 25%;

ii) the following warning statements are required on the medicine label:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);

- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';

- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);

iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:

- (IRRIT) 'If irritation develops, discontinue use'.

2306	GELATIN	A, E	
2307	GELIDIUM AMANSII	A, H	Iodine is a mandatory component of <i>Gelidium amansii</i> . Only for external use when the

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

Volume 3

			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.
2308	GELLAN GUM	E	
2309	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%.
2310	GELSEMIUM POWDER	A, H	
2311	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%.
2312	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%.
2313	GENTIAN DRY	A, H	
2314	GENTIAN POWDER	A, H	
2315	GENTIANA LUTEA	A, E, H	
2316	GENTIANA MACROPHYLLA	A, H	
2317	GENTIANA RHODANTHA	A, H	
2318	GENTIANA SCABRA	A, H	
2319	GENTIANELLA AMARELLA	A, H	
2320	GERANIAL	E	Permitted for use only in

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

Volume 3

			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%.
2321	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%.
2322	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%.
2323	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%.
2324	GERANIUM MACULATUM	A, E, H	
2325	GERANIUM OIL	A, E, H	
2326	GERANIUM OIL SAPONIFIED	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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

Volume 3

			1%.
2327	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%.
2328	GERANIUM ROBERTIANUM	A, E, H	
2329	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%.
2330	GERANIUM SIBIRICUM	A, E, H	
2331	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%.
2332	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%.

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

Volume 3

2333	GERANYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2334	GERANYL CROTONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2335	GERANYL ETHYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2336	GERANYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2337	GERANYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a</p>

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

Volume 3

			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2338	GERANYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2339	GERANYL NITRILE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2340	GERANYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2341	GERANYL TIGLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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

Volume 3

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2342	GEUM RIVALE	A, H	
2343	GEUM URBANUM	A, H	
2344	GHATTI GUM	A, E, H	
2345	GIGARTINA MAMILLOSA	A, H	Iodine is a mandatory component of Gigartina mamilliosa. 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.
2346	GINGER DRY	A, E, H	
2347	GINGER OIL	A, E, H	
2348	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%.
2349	GINGER POWDER	A, E, H	
2350	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.



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

Volume 3

2351	GLACIAL ACETIC ACID	E, H	The concentration in the medicine must be no more than 1.5%.
2352	GLECHOMA HEDERACEA	A, H	
2353	GLECHOMA LONGITUBA	A, H	
2354	GLEDITSIA AUSTRALIS	A, H	
2355	GLEDITSIA SINENSIS	A, H	
2356	GLEHNSIA LITTORALIS	A, H	
2357	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%.
2358	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2359	GLUCONOLACTONE	E	
2360	GLUCOSAMINE HYDROCHLORIDE	A, E	
2361	GLUCOSAMINE SULFATE	A	
2362	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.'
2363	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	
2364	GLUCOSE	A, E, H	
2365	GLUCOSE GLUTAMATE	E	Only for use in topical medicines

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

Volume 3

			for dermal application.
2366	GLUCOSE MONOHYDRATE	A, E, H	
2367	GLUCOSYLROUTIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.1%.
2368	GLUTAMIC ACID	A, E	Only for use in topical medicines for dermal application.
2369	GLUTAMIC ACID HYDROCHLORIDE	A, E, H	
2370	GLUTAMINE	A, E, H	
2371	GLUTARAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2372	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).
2373	GLUTEN-FREE WHEAT STARCH	E	
2374	GLYCERETH-26	E	Only for use in topical medicines for dermal application and not to

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

Volume 3

			<p>be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 7%.</p>
2375	GLYCEROL	A, E	When used as an active ingredient, it is only for use in topical medicines for dermal application.
2376	GLYCEROL ESTER OF PARTIALLY HYDROGENATED GUM ROSIN	E	<p>Only for use when the dosage form is 'chewing gum'.</p> <p>Must comply with:</p> <p>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</p> <p>b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopoeia-National Formulary, as in force or existing from time to time.</p>
2377	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.
2378	GLYCERYL BEHENATE	E	<p>Behenic acid is a mandatory component of glyceryl behenate.</p> <p>When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.</p> <p>In medicines for topical use, the concentration of glyceryl behenate</p>

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

Volume 3

			must be no more than 5%.
2379	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%.
2380	GLYCERYL DIISOSTEARATE	E	For use in topical medicines for dermal application.
2381	GLYCERYL DILAURATE	E	Only for use in topical medicines for dermal application.
2382	GLYCERYL DIOLEATE	E	Only for use in topical medicines for dermal application.
2383	GLYCERYL DISTEARATE	E	Only for use in topical medicines for dermal application.
2384	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%.
2385	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%.
2386	GLYCERYL LAURATE	E	Only for use in topical medicines for dermal application.
2387	GLYCERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2388	GLYCERYL LINOLENATE	E	Only for use in topical medicines

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

Volume 3

			for dermal application.
2389	GLYCERYL MONO AND DICAPRYLOCAPRATE	E	<p>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.</p> <p>The maximum recommended oral daily dose of the medicine must not provide more than 8 mg of glyceryl mono and dicaprylocaprate.</p> <p>The total concentration of fragrance proprietary excipient formulations containing glyceryl mono and dicaprylocaprate must not be more than 1% of the total medicine.</p>
2390	GLYCERYL MONOOLEATE	E	
2391	GLYCERYL MONOSTEARATE	E	
2392	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2393	GLYCERYL OLEATE CITRATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 4% of the formulation.</p>
2394	GLYCERYL PALMITO-STEARATE	E	
2395	GLYCERYL POLYACRYLATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.15%.</p>
2396	GLYCERYL	E	Only for use in topical medicines

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

Volume 3

	POLYMETHACRYLATE		for dermal application.
2397	GLYCERYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2398	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 Pharmacopoeia National Formulary, as in force or existing from time to time.
2399	GLYCERYL SORBITAN OLEOSTEARATE	E	Only for use in topical medicines for dermal application.
2400	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.
2401	GLYCERYL STEARATE CITRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
2402	GLYCERYL TRIACETYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 6%.

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

Volume 3

2403	GLYCERYL TRIACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2404	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%.
2405	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%.
2406	GLYCINE	A, E	
2407	GLYCINE MAX	A, E, H	
2408	GLYCOGEN	E	Only for use in topical medicines for dermal application.
2409	GLYCOL DISTEARATE	E	Only for use in topical medicines for dermal application.
2410	GLYCOLIC ACID	E	Only for use in topical medicines for dermal application. Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose. When present as an excipient in sunscreens, the concentration in the medicine must be no more than 5%. When used as an excipient ingredient in other medicines the concentration in the medicine

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

Volume 3

			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.
2411	GLYCYRRHIZA GLABRA	A, E, H	
2412	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%.
2413	GLYCYRRHIZA URALENSIS	A, E, H	
2414	GLYCYRRHIZINIC ACID	E	
2415	GNAPHALIUM AFFINE	A, H	
2416	GNAPHALIUM POLYCEPHALUM	A, H	
2417	GNAPHALIUM ULIGINOSUM	A, H	
2418	GOAT	H	Only for use as an active homoeopathic ingredient.
2419	GOAT MILK	E	
2420	GOLD	E, H	Only for use as an active homoeopathic or excipient ingredient.
2421	GOLD CHLORIDE	H	Only for use as an active homoeopathic ingredient.
2422	GOLDEN ROD HERB DRY	A, E, H	
2423	GOLDEN SEAL ROOT DRY	A, H	
2424	GOLDEN SEAL ROOT POWDER	A, H	
2425	GOLDEN SYRUP	E	When the route of administration of the medicine is oral or sublingual, sucrose is a mandatory component of golden syrup.
2426	GOMPHRENA GLOBOSA	A, H	
2427	GOSSYPIUM HERBACEUM	A, E, H	



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

Volume 3

2428	GRAPE	E	
2429	GRAPE SEED OIL	E	
2430	GRAPE WINE RED	E	Ethanol is a mandatory component of grape wine red.
2431	GRAPE WINE SHERRY	E	Ethanol is a mandatory component of grape wine sherry.
2432	GRAPE WINE WHITE	E	Ethanol is a mandatory component of grape wine white.
2433	GRAPEFRUIT	E	
2434	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%.
2435	GRAPEFRUIT OIL COLDPRESSED	A, E, H	
2436	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%.
2437	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%.

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

Volume 3

2438	GRAPEFRUIT OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2439	GRAPHITE	H	Only for use as an active homoeopathic ingredient.
2440	GRATIOLA LINIFOLIA	A, H	
2441	GREATER NETTLE HERB DRY	A, H	
2442	GREATER NETTLE HERB POWDER	A, H	
2443	GREATER NETTLE ROOT DRY	A, H	
2444	GREATER NETTLE ROOT POWDER	A, H	
2445	GREEN LIPPED MUSSEL	A	The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
2446	GREEN LIPPED MUSSEL DRIED	A	The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
2447	GREEN LIPPED MUSSEL OIL	A	The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
2448	GREEN S	E	Only for use as a colour in topical and oral medicines.
2449	GRIFOLA FRONDOSA	A	When the route of administration is oral or sublingual, the medicine

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

Volume 3

			requires the following warning statement on the medicine label: -(WARF) 'Do not take while on warfarin therapy without medical advice.'
2450	GRINDELIA CAMPORUM	A, H	
2451	GRINDELIA ROBUSTA	A, H	
2452	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%.
2453	GROUND IVY HERB DRY	A, H	
2454	GROUND IVY HERB POWDER	A, H	
2455	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%.
2456	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%.
2457	GUAIACUM OFFICINALE	A, E, H	
2458	GUAIACUM RESIN	A, E, H	
2459	GUAIACUM SANCTUM	A, H	
2460	GUAIENE	E	Permitted for use only in

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

Volume 3

			<p>combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2461	GUAIYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2462	GUANINE	E	<p>Only for use as an excipient in topical medicines for dermal application.</p>
2463	GUANOSINE	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration must be no more than 0.01% in the medicine.</p>
2464	GUAR GALACTOMANNAN	A	<p>When for oral use:</p> <p>(a) the maximum daily dose must provide no more than 25 g of guar galactomannan;</p> <p>(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)</p> <p>(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).</p>

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

Volume 3

2465	GUAR GUM	A, E, H	
2466	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	E	Only for use as an excipient in topical medicines for dermal application.
2467	GUAREA RUSBYI	A, H	
2468	GUAVA	E	
2469	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%.
2470	GYMNADENIA NIGRA	A	
2471	GYMNEMA SYLVESTRE	A, H	
2472	GYMNOCLADUS DIOICA	A, H	
2473	GYNOSTEMMA PENTAPHYLLUM	A	The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).
2474	HAHNEMANN'S SOLUBLE MERCURY	H	Only for use as an active homoeopathic ingredient.
2475	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

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

Volume 3

			<p>in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</p>
2476	HAMAMELIS LEAF DRY	A, H	
2477	HAMAMELIS LEAF POWDER	A, H	
2478	HAMAMELIS VIRGINIANA	A, E, H	
2479	HAMAMELIS WATER	A, E, H	
2480	HANDROANTHUS HEPTAPHYLLUS	A, H	
2481	HANDROANTHUS IMPETIGINOSUS	A, E, H	
2482	HARD FAT	E	
2483	HARD PARAFFIN	E	
2484	HARICOT BEAN	E	
2485	HARPAGOPHYTUM PROCUMBENS	A, E, H	

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

Volume 3

2486	HARUNGANA MADAGASCARIENSIS	A, H	
2487	HAZEL NUT	E	
2488	HAZEL NUT OIL	E	
2489	HEAVY KAOLIN	E	
2490	HEAVY MAGNESIUM OXIDE	A, E, H	<p>Magnesium is a mandatory component of heavy magnesium oxide.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
2491	HECTORITE	E	Only for use in topical medicines for dermal application.
2492	HEDEOMA PULEGIOIDES	A	

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

Volume 3

2493	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%.
2494	HEDTA	E	Only for use as an excipient in topical medicines for dermal application.
2495	HEKLA LAVA	H	Only for use as an active homoeopathic ingredient.
2496	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%.
2497	HELIANTHEMUM NUMMULARIUM	A, H	
2498	HELIANTHUS ANNUUS	A, E, H	
2499	HELIANTHUS TUBEROSUS	A, H	
2500	HELICHRYSUM ANGUSTIFOLIUM	A, E, H	
2501	HELICHRYSUM ARENARIUM	A, H	
2502	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%.
2503	HELLEBORUS NIGER	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2504	HELLEBORUS VIRIDIS	A, H	The maximum recommended



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

Volume 3

			daily dose must be no more than 1mg of the equivalent dry herbal material.
2505	HELONIAS RHIZOME DRY	A, H	
2506	HELONIAS RHIZOME POWDER	A, H	
2507	HEMIDESMUS INDICUS	A, E, H	
2508	HEMP SEED OIL	A, E	<p>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.</p> <p>Cannabidiol and tetrahydrocannabinols are mandatory components of hemp seed oil.</p> <p>The total concentration of cannabidiol in hemp seed oil must not be more than 75 mg/kg.</p> <p>The total concentration of tetrahydrocannabinols in hemp seed oil must not be more than 10 mg/kg.</p> <p>The route of administration for medicines that contain hemp seed oil must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 36 g of hemp seed oil.</p> <p>The following warning statements (or words to that effect) are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- ‘Not for use in children under 2 years of age’; and</li> <li>- ‘Not to be taken on the same day with other products containing</li> </ul>

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

Volume 3

			hemp seed oil, including food sources’.
2509	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%.
2510	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%.
2511	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%.
2512	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%.
2513	HEPTYL ACETATE	E	Permitted for use only in

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

Volume 3

			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%.
2514	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%.
2515	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%.
2516	HERACLEUM HEMSLEYANUM	A, H	
2517	HERNIARIA GLABRA	A, H	
2518	HESPERIDIN	A, E	
2519	HESPEROCYPARIS MACROCARPA	A, H	
2520	HESPEROYUCCA WHIPPLEI	A, H	
2521	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%.
2522	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

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

Volume 3

			1%.
2523	HEXAMETHYLINDANOPYRAN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2524	HEXAN-1-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2525	HEXANE	E	<p>The concentration of the medicine must be no more than 0.029%.</p> <p>When used for a route of administration other than topical, the residual solvent limit for Hexane is 2.9 mg per recommended daily dose.</p>
2526	HEXANOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a</p>

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

Volume 3

			medicine must be no more than 1%.
2527	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%.
2528	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 %.
2529	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%.
2530	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%.
2531	HEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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

Volume 3

			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2532	HEXYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2533	HEXYL CAPROATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2534	HEXYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2535	HEXYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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

Volume 3

2536	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%.
2537	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2538	HEXYL NICOTINATE	E	
2539	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%.
2540	HEXYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2541	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%.
2542	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.

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

Volume 3

			The concentration of the medicine must be no more than 3%.
2543	HEXYLENE GLYCOL	E	Only for use as an excipient in topical medicines for dermal application.
2544	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).
2545	HIBISCUS ESCULENTUS	A, H	
2546	HIBISCUS MUTABILIS	A, H	
2547	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%.
2548	HIBISCUS SABDARIFFA	A, E, H	
2549	HIERACIUM PILOSELLA	A, H	
2550	HIGH AMYLOSE MAIZE STARCH	A, E, H	
2551	HIGH CHROMIUM YEAST	A, E	Chromium is a mandatory component of high chromium



			<p>yeast.</p> <p>The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic chromium sources.</p> <p>High chromium yeast is considered to be an organic form of chromium.</p>
2552	HIGH FRUCTOSE MAIZE SYRUP	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2553	HIGH MOLYBDENUM YEAST	A, E	<p>Molybdenum is a mandatory component of high molybdenum yeast.</p> <p>The maximum daily dose of molybdenum from high molybdenum yeast must be no more than 62.5 micrograms.</p>
2554	HIGH SELENIUM YEAST	A	<p>When for oral or sublingual use, selenium is a mandatory component of high selenium yeast.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (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.'</p>
2555	HIMANTHUS LANCIFOLIUS	A, E, H	

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

Volume 3

2556	HIPPOPHAE RHAMNOIDES	A, E, H	
2557	HIRSCHFELDIA INCANA	A, H	Allyl isothiocyanate is a mandatory component of <i>Hirschfeldia incana</i> 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%.
2558	HISTAMINE DIHYDROCHLORIDE	H	Only for use as an active homoeopathic ingredient.
2559	HISTIDINE	A	
2560	HISTIDINE HYDROCHLORIDE	A, E, H	
2561	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%.
2562	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%.
2563	HOLCUS LANATUS	A, H	
2564	HOLY THISTLE HERB DRY	A, H	
2565	HOLY THISTLE HERB POWDER	A, H	

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

Volume 3

2566	HOMALOMENA OCCULTA	A, H	
2567	HOMOSALATE	A, E	<p>For use as an active ingredient only in sunscreens for dermal application.</p> <p>For use as an excipient only in topical medicines for dermal application.</p> <p>Not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 15%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> <li>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</li> </ul>
2568	HONEY	A, E	<p>When the route of administration is oral, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).</li> </ul>
2569	HONEY BEE	H	Only for use as an active homoeopathic ingredient.
2570	HONEY EXTRACT	E	<p>Honey extract must not be included in medicines intended for use in the eye.</p> <p>The concentration of honey extract in the medicine must not be more than 1%.</p>
2571	HONEY POWDER	E	Permitted for use only in combination with other permitted

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

Volume 3

			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2572	HOP STROBILE DRY	A, H	
2573	HOP STROBILE POWDER	A, H	
2574	HOPS OIL	A, E, H	
2575	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.
2576	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.
2577	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%.
2578	HOTTONIA PALUSTRIS	A, H	
2579	HOUTTUYNIA CORDATA	A, H	
2580	HOVENIA DULCIS	A, H	
2581	HUMULUS LUPULUS	A, E, H	
2582	HYALURONIC ACID	E	Only for use as an excipient in topical medicines for dermal application.
2583	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.

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

Volume 3

2584	HYDRANGEA ARBORESCENS	A, H	
2585	HYDRANGEA PANICULATA	A, H	
2586	HYDRASTIS CANADENSIS	A, E, H	
2587	HYDRATED SILICA	E	Only for use when the route of administration is other than inhalation.
2588	HYDROCHLORIC ACID	E	The concentration of the medicine must be no more than 0.5%.
2589	HYDROCOTYLE UMBELLATA	A, H	
2590	HYDROGEN CYANIDE	H	Only for use as an active homoeopathic ingredient.
2591	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.
2592	HYDROGENATED BUTYLENE/ETHYLENE/STYRENE COPOLYMER	E	Only for use in topical medicines for dermal application. The combined concentration of hydrogenated butylene/ethylene/styrene copolymer and hydrogenated ethylene/propylene/styrene copolymer in the medicine must be no more than 9%.

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

Volume 3

2593	HYDROGENATED C6-14 OLEFIN POLYMERS	E	<p>Only permitted for use in solid or semi-solid medicines for dermal application or in topical medicines for dermal application:</p> <p>(a) containing 25% or less of hydrocarbons, liquid; or</p> <p>(b) when packed in pressurised spray packs; or</p> <p>(c) when packed in containers with a capacity of 2 millilitres or less.</p> <p>Not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 7%.</p>
2594	HYDROGENATED CASTOR OIL	E	
2595	HYDROGENATED COCO-GLYCERIDES	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p>
2596	HYDROGENATED COCONUT OIL	E	
2597	HYDROGENATED COTTONSEED OIL	E	
2598	HYDROGENATED DIMER DILINOLEYL/DIMETHYLCARBONATE COPOLYMER	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 4% in the product.</p>
2599	HYDROGENATED ETHYLENE/PROPYLENE/STYRENE COPOLYMER	E	<p>The combined concentration of hydrogenated ethylene/propylene/styrene copolymer must be no more than 9%.</p>
2600	HYDROGENATED LANOLIN	E	

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

Volume 3

2601	HYDROGENATED LECITHIN	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p>
2602	HYDROGENATED PALM GLYCERIDES	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1.6%.</p>
2603	HYDROGENATED PALM GLYCERIDES CITRATE	E	<p>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.</p> <p>The concentration in the medicine must be no more than 0.01%.</p>
2604	HYDROGENATED PALM KERNEL OIL	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1.2%.</p>
2605	HYDROGENATED PALM OIL	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p> <p>Polycyclic aromatic hydrocarbons must be kept below the level of detection.</p>
2606	HYDROGENATED POLYDECENE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p>

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

Volume 3

2607	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.
2608	HYDROGENATED POLYISOBUTENE	E	Only for use in topical medicines for dermal application.
2609	HYDROGENATED SOYA OIL	E	
2610	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%.
2611	HYDROGENATED VEGETABLE OIL	E	
2612	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%.
2613	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%
2614	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%



2615	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%.
2616	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'.
2617	HYDROLYSED COLLAGEN	A, E	
2618	HYDROLYSED ELASTIN	E	Only for use in topical medicines for dermal application.
2619	HYDROLYSED GELATIN	A, E	
2620	HYDROLYSED GLYCOSAMINOGLYCANS	E	Only for use in topical medicines for dermal application.
2621	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%.
2622	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.

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

Volume 3

			The concentration in the medicine must be no more than 5%.
2623	HYDROLYSED MAIZE STARCH	E	
2624	HYDROLYSED MILK PROTEIN	E	
2625	HYDROLYSED RICE	A, E, H	
2626	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%.
2627	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%.
2628	HYDROLYSED VEGETABLE PROTEIN	E	
2629	HYDROLYSED WHEAT PROTEIN	E	Gluten is a mandatory component of hydrolysed wheat protein.
2630	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%.
2631	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%.
2632	HYDROQUINONE DIMETHYL ETHER	E	Permitted for use only in combination with other permitted

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

Volume 3

			<p>ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2633	HYDROUS WOOL FAT	A, E	<p>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.</p>
2634	HYDROXOCOBALAMIN	A	
2635	HYDROXYACETOPHENONE	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 1%.</p>
2636	HYDROXYAPATITE	A, E	
2637	HYDROXYCITRATE COMPLEX	A	<p>Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.</p>
2638	HYDROXYCITRIC ACID	A	
2639	HYDROXYCITRONELLAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a</p>

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

Volume 3

			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2640	HYDROXYCITRONELLAL DIMETHYL ACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2641	HYDROXYCITRONELLAL- METHYLANTHRANILATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2642	HYDROXYCITRONELLOL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2643	HYDROXYETHYL CETEARAMIDOPROPYLDIMONI UM CHLORIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>

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

Volume 3

2644	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%.
2645	HYDROXYLATED LANOLIN	E	
2646	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%.
2647	HYDROXYLYSINE	A, E	
2648	HYDROXYMETHYLCELLULOSE	E	
2649	HYDROXYOCTACOSANYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
2650	HYDROXPALMITOYL 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%.
2651	HYDROXYPROLINE	A, E	
2652	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

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

Volume 3

			than 4%. When for internal use, the maximum recommended daily dose must not contain more than 240mg of hydroxypropyl distarch phosphate.
2653	HYDROXYPROPYL STARCH	E	
2654	HYDROXYPROPYLBETADEX	E	Only for use in topical medicines for dermal application.
2655	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%.
2656	HYETELLOSE	E	
2657	HYLOCEREUS LEMAIREI	E	Permitted for use only as a colour for oral and topical use.
2658	HYLOCEREUS UNDATUS	A, H	
2659	HYMETELLOSE	E	
2660	HYOSCYAMUS LEAF DRY	A, H	Alkaloids calculated as hyoscyamine and hyoscyne are mandatory components of Hyoscamus leaf dry. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of hyoscyne in the medicine must be no more than than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2661	HYOSCYAMUS LEAF POWDER	A, H	Alkaloids calculated as hyoscyamine and hyoscyne are mandatory components of Hyoscamus leaf powder. The concentration of alkaloids

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

Volume 3

			calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of hyoscyamine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2662	HYOSCYAMUS NIGER	A, H	Alkaloids calculated as hyoscyamine and hyoscyamine are mandatory components of <i>Hyoscyamus niger</i> . The concentration of hyoscyamine in the medicine must be no more than 3 micrograms/kg or 3 micrograms/L or 0.3%. The concentration of hyoscyamine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2663	HYPERICUM ASCYRON	A, H	
2664	HYPERICUM JAPONICUM	A, H	
2665	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.'
2666	HYPROLOSE	E	
2667	HYPROMELLOSE	E	
2668	HYPROMELLOSE PHTHALATE	E	
2669	HYPTIS SUAVEOLENS	A, H	
2670	HYSSOPUS OFFICINALIS	A, E, H	
2671	IBERIS AMARA	A, H	
2672	ICHTHAMMOL	H	Only for use as an active homoeopathic ingredient.

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

Volume 3

2673	ILEX AQUIFOLIUM	A, H	
2674	ILEX CHINENSIS	A, H	
2675	ILEX PARAGUARIENSIS	A, E, H	<p>Caffeine is a mandatory component of <i>Ilex paraguariensis</i>.</p> <p>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%.</p> <p>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.</p> <p>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%.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect).</li> <li>- (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.'</li> </ul>



			<p>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</p> <p>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:</p> <p>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</p> <p>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</p>
2676	ILEX ROTUNDA	A, H	
2677	ILEX VERTICILLATA	A, H	
2678	ILLICIAM VERUM	A, H	<p>When the plant preparation is oil or distillate, and the concentration of Illicium verum oil or distillate in the preparation is greater than 50%:</p> <p>(a) the nominal capacity of the container must not be more than 50 millilitres;</p> <p>(b) a restricted flow insert must be fitted on the container; and</p> <p>(c) the following warning statement is required on the label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
2679	IMIDUREA	E	Only for use in topical medicines for dermal application.

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

Volume 3

2680	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%.
2681	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%.
2682	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%.
2683	IMPATIENS BALSAMINA	A, H	
2684	IMPATIENS GLANDULIFERA	A, H	
2685	IMPERATA CYLINDRICA	A, E, H	
2686	INDIGO CARMINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2687	INDIGO CARMINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2688	INDIGOFERA TINCTORIA	A, H	
2689	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%.

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

Volume 3

2690	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.
2691	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%.
2692	INDUSTRIAL METHYLATED SPIRIT	E	
2693	INOSITOL	A, E	
2694	INULA BRITANNICA	A, H	
2695	INULA HELENIUM	A, E, H	
2696	INULA RACEMOSA	A, H	
2697	INULIN	A, E	
2698	INULIN LAURYL CARBAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1.2%.
2699	INVERT SUGAR	E	
2700	INVERT SYRUP	E	When the route of administration is oral or sublingual, glucose is a mandatory component of Invert syrup.
2701	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%

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

Volume 3

			or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2702	IODOPROPYNYL BUTYLCARBAMATE	E	For use as an excipient ingredient in topical medicines only. The concentration in aqueous medicines must be no more than 10%.
2703	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%.
2704	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%.
2705	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%.
2706	IPECACUANHA POWDER	A, H	Emetine is a mandatory component of Ipecacuanha Powder. The concentration of emetine in

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

Volume 3

			the medicine must be no more than 0.2%.
2707	IPECACUANHA PREPARED	A, H	<p>Emetine is a mandatory component of Ipecacuanha Prepared.</p> <p>The concentration of emetine in the medicine must be no more than 0.2%.</p>
2708	IPECACUANHA ROOT LIQUID EXTRACT	A, H	<p>Emetine is a mandatory component of Ipecacuanha root liquid extract.</p> <p>The concentration of emetine in the medicine must be no more than 0.2%.</p>
2709	IPOMOEA BATATAS	A, H	
2710	IPOMOEA JALAPA	A, H	
2711	IRIDOPHYCUS FLACCIDUM	A, H	<p>Iodine is a mandatory component of Iridophycus flaccidum.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
2712	IRIS DOMESTICA	A, H	
2713	IRIS FLORENTINA	A, H	
2714	IRIS GERMANICA	A, H	
2715	IRIS PALLIDA	A, H	
2716	IRIS TENAX	H	
2717	IRIS VERSICOLOR	A, H	
2718	IRON	A, H	<p>Only for use in oral medicines.</p> <p>When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of</p>

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

Volume 3

---

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).

---

2719	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

---

			<p>dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>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).</p>
2720	IRON (II) GLYCINATE	A	<p>Only for use in oral medicines.</p> <p>Iron is a mandatory component of iron (II) glycinate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to</p>

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

Volume 3

			<p>10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2721	IRON (III) GLYCINATE	A	<p>Only for use in oral medicines.</p> <p>Iron is a mandatory component of iron (III) glycinate.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the</p>



---

			<p>primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2722	IRON AMINO ACID CHELATE	A, H	<p>Only for use in oral medicines.</p> <p>When used internally, iron is a mandatory component of iron amino acid chelate.</p> <p>The concentration of iron in iron amino acid chelate must be no more than 25%.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as</p>

---

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

Volume 3

			<p>an excipient), the primary pack must contain no more than 750 mg of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).</p> <p>Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims, the following warning statement is required on the label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2723	IRON OXIDE BLACK	E	<p>Permitted for use only as a colour in medicines limited to topical and oral routes of administration.</p> <p>When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration</p>

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

Volume 3

			in the medicine must be no more than 10 mg per dosage unit.
2724	IRON OXIDE RED	E	<p>Permitted for use only as a colour in medicines limited to topical and oral routes of administration.</p> <p>When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.</p>
2725	IRON OXIDE YELLOW	E	<p>Permitted for use only as a colour in medicines limited to topical and oral routes of administration.</p> <p>When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.</p> <p>When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.</p>
2726	IRON PHOSPHATE	A, E, H	<p>When used internally, iron is a mandatory component of iron phosphate and must be declared.</p> <p>When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron.</p> <p>If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg</p>

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

Volume 3

			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).
2727	IRONE	E	
2728	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%.
2729	ISATIS TINCTORIA	A, H	
2730	ISOAMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2731	ISOAMYL 2-METHYLBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2732	ISOAMYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2733	ISOAMYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2734	ISOAMYL BENZOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a</p>

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

Volume 3

			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2735	ISOAMYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2736	ISOAMYL CAPRYLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2737	ISOAMYL CINNAMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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

Volume 3

2738	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%.
2739	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%.
2740	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%.
2741	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%.

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

Volume 3

2742	ISOAMYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2743	ISOAMYL LAURATE	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration must be no more than 12%.</p>
2744	ISOAMYL METHOXYCINNAMATE	A	<p>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.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> <li>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</li> </ul>
2745	ISOAMYL PHENYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>



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

Volume 3

			flavour concentration in a 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 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%.
2747	ISOAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2748	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%.
2749	ISOBERGAMIATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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

Volume 3

			fragrance concentration in a medicine must be no more than 1%.
2750	ISOBORNEOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2751	ISOBORNYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2752	ISOBORNYL CYCLOHEXANOL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2753	ISOBUTANE	E	Only for use in topical medicines for dermal application.
2754	ISOBUTYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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

Volume 3

			flavour concentration in a 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	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.
2756	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%.
2757	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%.
2758	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%.
2759	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

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

Volume 3

			medicine must be no more than 5%.
2760	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%.
2761	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%.
2762	ISOBUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
2763	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%.
2764	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%.
2765	ISOBUTYL PHENYLACETATE	E	Permitted for use only in

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

Volume 3

			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2766	ISOBUTYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2767	ISOBUTYL QUINOLINE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2768	ISOBUTYL SALICYLATE	E	<p>Only for use in topical medicines for dermal application.</p>
2769	ISOBUTYLENE/ISOPRENE COPOLYMER	E	<p>Only for oral use when the dosage form is chewing gum.</p> <p>The concentration must be consistent with best practice for the production of gum delivery systems.</p>
2770	ISOBUTYRALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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

Volume 3

				5%.
2771	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%.	
2772	ISOCETYL ALCOHOL	E	Only for use in topical medicines for dermal application.	
2773	ISOCETYL LINOLEOYL STEARATE	E	Only for use in topical medicines for dermal application.	
2774	ISOCETYL STEARATE	E	Only for use in topical medicines for dermal application.	
2775	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%.	
2776	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%.	
2777	ISODECYL ISONONANOATE	E	Only for use in topical medicines for dermal application.	
2778	ISODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.	

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

Volume 3

2779	ISODECYL OLEATE	E	Only for use in topical medicines for dermal application.
2780	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%.
2781	ISODODECANE	E	Only for use in topical medicines for dermal application.
2782	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%.
2783	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%.
2784	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

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

Volume 3

			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2785	ISOEUGENYL BENZYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2786	ISOHEXADECANE	E	<p>Only for use in topical medicines for dermal application.</p>
2787	ISOJASMONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must not be more than 5%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must not be more 1%.</p>
2788	ISOLEUCINE	A, E	
2789	ISOMALT	E	
2790	ISOMENTHONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>



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

Volume 3

2791	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%.
2792	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%.
2793	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%.
2794	ISOPENTANE	E	For dental use only. The concentration must be no more than 2%.
2795	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%.
2796	ISOPHORONE	E	Permitted for use only in combination with other permitted

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

Volume 3

			<p>ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>The total concentration of isophorone in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
2797	ISOPHYTOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2798	ISOPROPYL 2-METHYLBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2799	ISOPROPYL 4-HYDROXYBENZOATE	E	<p>Only for use in topical medicines for dermal application.</p>
2800	ISOPROPYL ACETATE	E	<p>Only for use in topical medicines for dermal application.</p>
2801	ISOPROPYL ALCOHOL	E	
2802	ISOPROPYL CAPROATE	E	<p>Permitted for use only in combination with other permitted</p>

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

Volume 3

			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2803	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%.
2804	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
2805	ISOPROPYL LANOLATE	E	Only for use in topical medicines for dermal application.
2806	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%.
2807	ISOPROPYL MYRISTATE	E	
2808	ISOPROPYL PALMITATE	E	Only for use in topical medicines for dermal application.
2809	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%.
2810	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2811	ISOPROPYL TITANIUM	E	Only for use in topical medicines

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

Volume 3

	TRIISOSTEARATE		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%.
2812	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%.
2813	ISOPULEGOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2814	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%.
2815	ISOSTEARIC ACID	E	Only for use in topical medicines for dermal application.
2816	ISOSTEAROYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration must be no more than 0.3%.

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

Volume 3

2817	ISOSTEARYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2818	ISOSTEARYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2819	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%.
2820	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%.
2821	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%.
2822	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

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

Volume 3

			fragrance concentration in a medicine must be no more 1%.
2823	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).
2824	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).
2825	IVA AXILLARIS	A, H	
2826	JAMAICA DOGWOOD BARK DRY	A, H	
2827	JAMAICA DOGWOOD BARK POWDER	A, H	
2828	JASMINE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2829	JASMINE LACTONE	E	Only for use in topical medicines for dermal application.
2830	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

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

Volume 3

			1%.
2831	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%.
2832	JASMINUM OFFICINALE	A, E, H	
2833	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%.
2834	JATEORHIZA PALMATA	A, H	
2835	JATROPHA CURCAS	H	Only for use as an active homoeopathic ingredient
2836	JERUSALEM ARTICHOKE	E	
2837	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%.
2838	JUGLANS CINEREA	A, E, H	
2839	JUGLANS NIGRA	A, E, H	
2840	JUGLANS REGIA	A, H	
2841	JUNCUS EFFUSUS	A, H	
2842	JUNIPER BERRY OIL	A, E, H	
2843	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

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

Volume 3

---

---

			1%.
2844	JUNIPERUS CALIFORNICA	A, H	
2845	JUNIPERUS COMMUNIS	A, E, H	
2846	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%.
2847	JUNIPERUS OXYCEDRUS	A, H	
2848	JUNIPERUS VIRGINIANA	A, E, H	
2849	JUSTICIA ADHATODA	A, H	

---

---



