

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

(section 4)

Part 1 – Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2140	FABIANA IMBRICATA	A, H	
2141	FAGOPYRUM ESCULENTUM	A, H	
2142	FAGUS GRANDIFOLIA	A, H	
2143	FAGUS SYLVATICA	A, H	
2144	FALLOPIA MULTIFLORA	A, H	When for oral use, the medicine requires the following warning statement on the medicine label: - (FALLMUL) 'Warning: Fallopia multiflora may harm the liver in some people. Use under the supervision of a healthcare professional.'
2145	FARNESOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2146	FARNESYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
2147	FAST GREEN FCF	E	Permitted for use only as a colour for oral and topical use.
2148	FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

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			<p>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>
2149	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>
2150	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>
2151	FENNEL BITTER SEED DRY	A, E, H	When used in oral medicines and the medicine is listed in the

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			<p>Register on or after 1 October 2017 the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.' <p>When used in oral medicines and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statements on the medicine label if supplied after 1 April 2019:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.'

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2152	FENNEL LEAF	E	
2153	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 medicine requires the following warning statement on the medicine 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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended.'</p> <p>- (PREGNT2) 'Do not use if</p>

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			<p>pregnant or likely to become pregnant (or words to that effect).'</p> <p>- (BREASF) 'Do not use while breastfeeding.'</p> <p>When used in oral medicines and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statements on the medicine label if supplied after 1 April 2019:</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>
2154	FENNEL SWEET SEED DRY	A, E, H	<p>When used in oral medicines and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not</p>

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			<p>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> <p>When used in oral medicines and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statements on the medicine label if supplied after 1 April 2019:</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>
2155	FENUGREEK	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total</p>

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			flavour concentration in a medicine must be no more than 5%.
2156	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%.
2157	FERRIC AMMONIUM CITRATE	A, E, H	<p>When for internal use, iron is a mandatory component of ferric ammonium citrate.</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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> <p>When for internal use except for iron-containing multivitamin/mineral products</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2158	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</p>

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			<p>(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:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2159	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 child</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
2160	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</p>

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			<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 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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2161	FERRIC OXIDE	E	
2162	FERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2163	FERRIC PYROPHOSPHATE	A, H	<p>When for internal use, iron is a mandatory component of ferric pyrophosphate.</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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2164	FERROSO FERRIC 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>

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2165	FERROSFERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2166	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 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
2167	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2168	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 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2169	FERROUS IODIDE	H	Only for use as an active homoeopathic ingredient.
2170	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</p>

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			<p>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 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
2171	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 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</p>

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

Table 1 **Part 1**

Volume 3

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
2172	FERROUS PICRATE	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2173	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 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			indicated for general nutritional support that do not make specific iron-deficiency related claims, the medicine requires the following statement on the medicine label: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2174	FERROUS 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 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2175	FERULA ASSA-FOETIDA	A, E, H	
2176	FERULA FOETIDA	A, E, H	
2177	FERULA GALBANIFLUA	A, E, H	
2178	FERULA RUBRICAULIS	A, E, H	

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2179	FERULA SUMBUL	A, H	
2180	FERULIC ACID	E	Only for use in topical medicines for dermal application.
2181	FESTUCA ELATIOR	A, H	
2182	FEVERFEW HERB DRY	A, H	
2183	FEVERFEW HERB POWDER	A, H	
2184	FICUS CARICA	A, E, H	
2185	FICUS PUMILA	A, H	
2186	FIG	E	
2187	FIG DRY	A, H	
2188	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</p>

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			<p>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"> - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. <p>In addition, when the ingredient is included in a medicine that is listed in the Register:</p> <ul style="list-style-type: none"> - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b).</p> <p>a) The following warning statement is required on the medicine label:</p> <p>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</p> <p>b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</p> <p>- (IRRIT) 'If irritation</p>

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			develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
2189	FIR BALSAM ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2190	FIR NEEDLE OIL CANADIAN	A, E	
2191	FIR NEEDLE OIL SIBERIAN	A, E	
2192	FIRMIANA SIMPLEX	A, E, H	
2193	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2194	FLEMINGIA MACROPHYLLA	A, H	
2195	FLOUVE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2196	FLUORESCHEIN SODIUM	E	
2197	FOENICULUM VULGARE	A, E, H	<p>When used in oral medicines and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (BREASF) 'Do not use while breastfeeding.' <p>When used in oral medicines and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statements on the medicine label if supplied after 1 April 2019:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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> <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 fitted on the container, and the medicine requires the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2198	FOLIC ACID	A	<p>When for internal use, the maximum recommended daily dose must be no more than 500 micrograms of folic acid.</p> <p>When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose.</p> <p>When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects:</p> <p>a) the maximum daily dose must provide 400 – 500 micrograms of folic acid; and</p> <p>b) the following statement must be included on the label:</p> <p>- (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2199	FOOD ORANGE 6	E	Permitted for use only as a colour for oral and topical use.
2200	FOOD ORANGE 7	E	Permitted for use only as a colour for oral and topical use.
2201	FOOD RED 13	E	Permitted for use only as a colour for topical use.
2202	FORMALDEHYDE/MELAMINE/TOSYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
2203	FORMIC ACID	H	Only for use as an active homoeopathic ingredient.
2204	FORSYTHIA SUSPensa	A, H	
2205	FORTIFIED WINE	E	Ethanol is a mandatory component of fortified wine. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			label: - (ETHAN) 'Contains ethanol or contains alcohol'.
2206	FRACTIONATED COCONUT OIL	E	
2207	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.
2208	FRAGARIA CHILOENSIS	A, E, H	
2209	FRAGARIA VESCA	A, E, H	
2210	FRAGARIA VIRGINIANA	A, E, H	
2211	FRAGARIA X ANANASSA	A, E, H	
2212	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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]. <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' [or words to that effect]. <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s)]

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>or the chemical component(s)']; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
2213	FRANGULA BARK POWDER	A, H	<p>Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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]'. <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water [or words to that effect]'. <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s)]'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>or the chemical component(s)']; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water [or words to that effect]'; and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
2214	FRANGULA PURSHIANA	A, H	<p>When for oral use, hydroxyanthracene derivatives calculated as cascarioside A is a mandatory component of Frangula purshiana.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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]. <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' [or words to that effect]. <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>contains [name of the herb(s) or the chemical component(s)]; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
2215	FRAXINUS AMERICANA	A, H	
2216	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A, H	
2217	FRAXINUS EXCELSIOR	A, H	The components Nuzhenide and secoiridoid glucoside GL3 are only available when the plant part is seed.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2218	FRAXINUS ORNUS	A, H	
2219	FRITILLARIA CIRRHOSA	A, H	
2220	FRITILLARIA THUNDBERGII	A, H	
2221	FRITILLARIA VERTICILLATA	A, H	
2222	FRUCTOOLIGOSACCHARIDES	A, E	
2223	FRUCTOSE	A, E, H	
2224	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>
2225	FUMARIA OFFICINALIS	A, E, H	
2226	FUMARIC ACID	E, H	Only for use as an active homoeopathic or excipient ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2227	FUMITORY HERB DRY	A, H	
2228	FUMITORY HERB POWDER	A, H	
2229	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%.
2230	FURFURAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2231	FURFURYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.
2232	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%.
2233	FURFURYL MERCAPTAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2234	FUSEL OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2235	GALBANUM OIL	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>
2236	GALBANUM PHENOL	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>
2237	GALBANUM RESIN	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2238	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%.
2239	GALEGA OFFICINALIS	A, H	
2240	GALEOPSIS SEGETUM	A, H	
2241	GALIUM APARINE	A, H	
2242	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%.
2243	GALIUM PALUSTRE	A, H	
2244	GALIUM VERUM	A, H	
2245	GALL STONE	H	Only for use as an active

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			homoeopathic ingredient.
2246	GALPHIMIA GLAUCA	A, H	
2247	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%.
2248	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%.
2249	GAMMA-CYCLODEXTRIN	E	
2250	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>a flavour 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>
2251	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>
2252	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
2253	GAMMA-HEXALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2254	GAMMA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2255	GAMMA-LINOLEIC ACID	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2256	GAMMA-LINOLENIC ACID	E	
2257	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%.
2258	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%.
2259	GAMMA-OCTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2260	GAMMA-TERPINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2261	GAMMA-TOCOPHEROL	E	
2262	GAMMA-UNDECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2263	GAMMA-VALEROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2264	GANODERMA LUCIDUM	A, E, H	
2265	GARCINIA GUMMI-GUTTA	A	Only for use in oral medicines. Must be obtained from the rind of the fruit only. Must not contain any directions for use for children or pregnant or lactating women.
2266	GARCINIA QUAESITA	A, H	
2267	GARDEN BEAN	E	
2268	GARDENIA JASMINOIDES	A, E	
2269	GARDENIA TAHITENSIS	E	Only for use in topical

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

Table 1 **Part 1**

Volume 3

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	FLOWER EXTRACT		medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%
2270	GARLIC BULB DRY	A, E, H	
2271	GARLIC BULB FRESH	A, H	
2272	GARLIC BULB POWDER	A, E, H	
2273	GARLIC CLOVE POWDER	A, H	
2274	GARLIC OIL	A, E, H	
2275	GASTRODIA ELATA	A, H	
2276	GAULTHERIA PROCUMBENS	A, E, H	Methyl salicylate is a mandatory component of Gaultheria procumbens. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5%

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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"> - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. <p>In addition, when the ingredient is included in a medicine that is listed in the Register:</p> <ul style="list-style-type: none"> - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>under (a) & (b); or</p> <p>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b).</p> <p>a) The following warning statement is required on the medicine label:</p> <p>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</p> <p>b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that</p>

Table 1 **Part 1**

Volume 3

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			effect); - (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
2277	GELATIN	A, E	
2278	GELIDIUM AMANSII	A, H	Iodine is a mandatory component of Gelidium amansii. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2279	GELLAN GUM	E	
2280	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2281	GELSEMIUM POWDER	A, H	
2282	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%.
2283	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%.
2284	GENTIAN DRY	A, H	
2285	GENTIAN POWDER	A, H	
2286	GENTIANA LUTEA	A, E, H	
2287	GENTIANA MACROPHYLLA	A, H	
2288	GENTIANA RHODANTHA	A, H	
2289	GENTIANA SCABRA	A, H	
2290	GENTIANELLA AMARELLA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2291	GERANIAL	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>
2292	GERANIC ACID	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>
2293	GERANIOL	E	<p>Permitted for use only:</p> <p>(a) in topical medicines for dermal application; and</p> <p>(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
2294	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%.
2295	GERANIUM MACULATUM	A, E, H	
2296	GERANIUM OIL	A, E, H	
2297	GERANIUM OIL SAPONIFIED	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2298	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
2299	GERANIUM ROBERTIANUM	A, E, H	
2300	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%.
2301	GERANIUM SIBIRICUM	A, E, H	
2302	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%.
2303	GERANYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2304	GERANYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2305	GERANYL CROTONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2306	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>
2307	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>
2308	GERANYL ISOBUTYRATE	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2309	GERANYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2310	GERANYL NITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2311	GERANYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2312	GERANYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2313	GEUM RIVALE	A, H	
2314	GEUM URBANUM	A, H	
2315	GHATTI GUM	A, E, H	
2316	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

Table 1 **Part 1**

Volume 3

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			300 micrograms of iodine per maximum recommended daily dose.
2317	GINGER DRY	A, E, H	
2318	GINGER OIL	A, E, H	
2319	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%.
2320	GINGER POWDER	A, E, H	
2321	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2322	GLACIAL ACETIC ACID	E, H	The concentration in the medicine must be no more than 1.5%.
2323	GLECHOMA HEDERACEA	A, H	
2324	GLECHOMA LONGITUBA	A, H	
2325	GLEDITSIA AUSTRALIS	A, H	
2326	GLEDITSIA SINENSIS	A, H	
2327	GLEHNNIA LITTORALIS	A, H	
2328	GLORIOSA SUPERBA	A, H	Colchicine is a mandatory component of <i>Gloriosa superba</i> 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%.
2329	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2330	GLUCONOLACTONE	E	
2331	GLUCOSAMINE HYDROCHLORIDE	A, E	When derived from seafood, the medicine requires the following warning statement

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>on the medicine label:</p> <p>- (SFOOD) 'Derived from seafood'.</p>
2332	GLUCOSAMINE SULFATE	A	<p>When derived from seafood, the medicine requires the following warning statement on the medicine label:</p> <p>- (SFOOD) 'Derived from seafood'.</p>
2333	GLUCOSAMINE SULFATE POTASSIUM CHLORIDE	A	<p>Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride.</p> <p>When derived from seafood, the medicine requires the following warning statement on the medicine label:</p> <p>- (SFOOD) 'Derived from seafood'.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (POTAS) 'Contains [amount of potassium in milligrams] mg of potassium. If you have kidney disease or are taking heart or blood pressure</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'
2334	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2335	GLUCOSE	A, E, H	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			label: - (LACT) 'Contains lactose' (or words to that effect).
2336	GLUCOSE GLUTAMATE	E	Only for use in topical medicines for dermal application.
2337	GLUCOSE MONOHYDRATE	A, E, H	<p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose monohydrate, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (LACT) 'Contains lactose' (or words to that effect).
2338	GLUCOSYLRUTIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
2339	GLUTAMIC ACID	A, E	Only for use in topical medicines for dermal application.
2340	GLUTAMIC ACID HYDROCHLORIDE	A, E, H	
2341	GLUTAMINE	A, E, H	
2342	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2343	GLUTATHIONE	A, E	<p>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.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (ADULT) 'Adults only' (or words to that effect).
2344	GLUTEN-FREE WHEAT STARCH	E	
2345	GLYCERETH-26	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 7%.</p>
2346	GLYCEROL	A, E	<p>When used as an active ingredient, it is only for use in topical medicines for dermal</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
2347	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>
2348	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 must be no more than</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
2349	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%.
2350	GLYCERYL DIISOSTEARATE	E	For use in topical medicines for dermal application.
2351	GLYCERYL DILAURATE	E	Only for use in topical medicines for dermal application.
2352	GLYCERYL DIOLEATE	E	Only for use in topical medicines for dermal application.
2353	GLYCERYL DISTEARATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2354	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%.
2355	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%.
2356	GLYCERYL LAURATE	E	Only for use in topical medicines for dermal application.
2357	GLYCERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2358	GLYCERYL LINOLENATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2359	GLYCERYL MONOOLEATE	E	
2360	GLYCERYL MONOSTEARATE	E	
2361	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2362	GLYCERYL OLEATE CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4% of the formulation.
2363	GLYCERYL PALMITO- STEARATE	E	
2364	GLYCERYL POLYACRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2365	GLYCERYL POLYMETHACRYLATE	E	Only for use in topical medicines for dermal application.
2366	GLYCERYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2367	GLYCERYL ROSINATE	E	<p>Only for use when the dosage form is 'chewing gum'.</p> <p>Must comply with:</p> <p>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</p> <p>b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia National Formulary, as in force or existing from time to time.</p>
2368	GLYCERYL SORBITAN OLEOSTEARATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2369	GLYCERYL STARCH	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 4%.</p> <p>The residual levels of epichlorohydrin are to be kept below the level of detection.</p>
2370	GLYCERYL STEARATE CITRATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 5%.</p>
2371	GLYCERYL TRIACETYL HYDROXYSTEARATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 6%.</p>
2372	GLYCERYL TRIACETYL RICINOLEATE	E	<p>Only for use in topical medicines for dermal application.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2373	GLYCERYL TRINITRATE	H	Only for use as an active homoeopathic ingredient.
2374	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%.
2375	GLYCINE	A, E	
2376	GLYCINE MAX	A, E, H	
2377	GLYCOGEN	E	Only for use in topical medicines for dermal application.
2378	GLYCOL DISTEARATE	E	Only for use in topical medicines for dermal application.
2379	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When present as an excipient in sunscreens, the concentration in the medicine must be no more than 5%.</p> <p>When used as an excipient ingredient in other medicines the concentration in the medicine must be no more than 20%.</p> <p>If the concentration is more than 5% but no more than 20%, the pH of the medicine must be 3.5 or greater.</p>
2380	GLYCYRRHIZA GLABRA	A, E, H	
2381	GLYCYRRHIZA SPECIES	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>
2382	GLYCYRRHIZA URALENSIS	A, E, H	
2383	GLYCYRRHIZINIC ACID	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2384	GNAPHALIUM AFFINE	A, H	
2385	GNAPHALIUM POLYCEPHALUM	A, H	
2386	GNAPHALIUM ULIGINOSUM	A, H	
2387	GOAT	H	Only for use as an active homoeopathic ingredient.
2388	GOAT MILK	E	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
2389	GOLD	E, H	Only for use as an active homoeopathic or excipient ingredient.
2390	GOLD CHLORIDE	H	Only for use as an active homoeopathic ingredient.
2391	GOLDEN ROD HERB DRY	A, E, H	
2392	GOLDEN SEAL ROOT DRY	A, H	
2393	GOLDEN SEAL ROOT POWDER	A, H	
2394	GOLDEN SYRUP	E	Sucrose is a mandatory

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>component of Golden syrup when the route of administration of the medicine is oral or sublingual.</p> <p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
2395	GOMPHRENA GLOBOSA	A, H	
2396	GOOSEBERRY	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2397	GOSSYPIUM HERBACEUM	A, E, H	
2398	GRAPE	E	
2399	GRAPE SEED OIL	E	
2400	GRAPE WINE RED	E	Ethanol is a mandatory component of Grape wine red. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2401	GRAPE WINE SHERRY	E	Ethanol is a mandatory component of Grape wine sherry. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2402	GRAPE WINE WHITE	E	Ethanol is a mandatory component of Grape wine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			white. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2403	GRAPEFRUIT	E	
2404	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%.
2405	GRAPEFRUIT OIL COLDPRESSED	A, E, H	
2406	GRAPEFRUIT OIL CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2407	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%.
2408	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%.
2409	GRAPHITE	H	Only for use as an active homeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2410	GRATIOLA LINIFOLIA	A, H	
2411	GREATER NETTLE HERB DRY	A, H	
2412	GREATER NETTLE HERB POWDER	A, H	
2413	GREATER NETTLE ROOT DRY	A, H	
2414	GREATER NETTLE ROOT POWDER	A, H	
2415	GREEN LIPPED MUSSEL	A	
2416	GREEN LIPPED MUSSEL DRIED	A	
2417	GREEN LIPPED MUSSEL OIL	A	
2418	GREEN S	E	Only for use as a colour in topical and oral medicines.
2419	GRIFOLA FRONDOSA	A	When the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: -(WARF) 'Do not take while on warfarin therapy without medical advice.'
2420	GRINDELIA CAMPORUM	A, H	
2421	GRINDELIA ROBUSTA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2422	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%.
2423	GROUND IVY HERB DRY	A, H	
2424	GROUND IVY HERB POWDER	A, H	
2425	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%.
2426	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
2427	GUAIACUM OFFICINALE	A, E, H	
2428	GUAIACUM RESIN	A, E, H	
2429	GUAIACUM SANCTUM	A, H	
2430	GUAIACWOOD ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2431	GUAIENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2432	GUAIYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2433	GUANINE	E	Only for use as an excipient in topical medicines for dermal application.
2434	GUANOSINE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 0.01% in the medicine.
2435	GUAR GALACTOMANNAN	A	When for oral use: (a) the maximum daily dose must provide no more than 25 g of guar galactomannan; (b) the medicine requires the following dosage instructions: - (FIBRE) 'The dose of fibre

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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:</p> <p>- (DNTPOW) 'Do not take powder alone. Mix with food or fluid.' (or words to that effect).</p>
2436	GUAR GUM	A, E, H	
2437	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	E	Only for use as an excipient in topical medicines for dermal application.
2438	GUAREA RUSBYI	A, H	
2439	GUAVA	E	
2440	GURJUN BALSAM	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2441	GYMNADENIA NIGRA	A	
2442	GYMNEMA SYLVESTRE	A, H	
2443	GYMNOCLADUS DIOICA	A, H	
2444	GYNOSTEMMA PENTAPHYLLUM	A	The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).
2445	GYNURA JAPONICA	A, H	
2446	HAHNEMANN'S SOLUBLE MERCURY	H	Only for use as an active homoeopathic ingredient.
2447	HALIBUT-LIVER OIL	A, E	<p>Colecalciferol and Vitamin A are mandatory components of Halibut-liver oil.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</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>

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

Table 1 **Part 1**

Volume 3

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2448	HAMAMELIS LEAF DRY	A, H	
2449	HAMAMELIS LEAF POWDER	A, H	
2450	HAMAMELIS VIRGINIANA	A, E, H	
2451	HAMAMELIS WATER	A, E, H	
2452	HANDROANTHUS HEPTAPHYLLUS	A, H	
2453	HANDROANTHUS IMPETIGINOSUS	A, E, H	
2454	HARD FAT	E	
2455	HARD PARAFFIN	E	
2456	HARICOT BEAN	E	
2457	HARPAGOPHYTUM PROCUMBENS	A, E, H	
2458	HARUNGANA MADAGASCARIENSIS	A, H	
2459	HAZEL NUT	E	
2460	HAZEL NUT OIL	E	
2461	HEAVY KAOLIN	E	
2462	HEAVY MAGNESIUM OXIDE	A, E, H	
2463	HECTORITE	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
2464	HEDEOMA PULEGIOIDES	A	
2465	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%.
2466	HEDTA	E	Only for use as an excipient in topical medicines for dermal application.
2467	HEKLA LAVA	H	Only for use as an active homoeopathic ingredient.
2468	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%.
2469	HELIANTHEMUM	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	NUMMULARIUM		
2470	HELIANTHUS ANNUUS	A, E, H	
2471	HELIANTHUS TUBEROSUS	A, H	
2472	HELICHRYSUM ANGUSTIFOLIUM	A, E, H	
2473	HELICHRYSUM ARENARIUM	A, H	
2474	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%.
2475	HELLEBORUS NIGER	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2476	HELLEBORUS VIRIDIS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2477	HELONIAS RHIZOME DRY	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2478	HELONIAS RHIZOME POWDER	A, H	
2479	HEMIDESMUS INDICUS	A, E, H	
2480	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%.
2481	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%.
2482	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2483	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%.
2484	HEPTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2485	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
2486	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%.
2487	HERACLEUM HEMSLEYANUM	A, H	
2488	HERNIARIA GLABRA	A, H	
2489	HESPERIDIN	A, E	
2490	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%.
2491	HEXAHYDRO-4,7-METHANOINDEN-6-YL PIVALATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2492	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>
2493	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2494	HEXANE	E	The concentration of the medicine must be no more than 0.029%. When used for a route of administration other than topical, the residual solvent limit for Hexane is 2.9 mg per recommended daily dose.
2495	HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2496	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
2497	HEXASODIUM FYTATE	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 of Hexasodium fytate in the medicine must be no more than 1.0 %.</p>
2498	HEXENAL	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>
2499	HEXYL 2-METHYLBUTYRATE	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
2500	HEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2501	HEXYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2502	HEXYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2503	HEXYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2504	HEXYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2505	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 1%.
2506	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2507	HEXYL NICOTINATE	E	
2508	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%.
2509	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%.
2510	HEXYLDECANOL	E	Only for use as an excipient in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			included in topical medicines intended for use in the eye. The concentration of the medicine must be no more than 3%.
2511	HEXYLENE GLYCOL	E	Only for use as an excipient in topical medicines for dermal application.
2512	HIBISCUS ESCULENTUS	A, H	
2513	HIBISCUS MUTABILIS	A, H	
2514	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%.
2515	HIBISCUS SABDARIFFA	A, E, H	
2516	HIERACIUM PILOSELLA	A, H	
2517	HIGH AMYLOSE MAIZE STARCH	A, E, H	
2518	HIGH CHROMIUM YEAST	A, E	Chromium is a mandatory component of high chromium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<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>
2519	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>
2520	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>
2521	HIGH SELENIUM YEAST	A	<p>When for oral or sublingual use, selenium is a mandatory component of high selenium</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
2522	HIMATANTHUS LANCIFOLIUS	A, E, H	
2523	HIPPOPHAE RHAMNOIDES	A, E, H	
2524	HIRSCHFELDIA INCANA	A, H	<p>Allyl isothiocyanate is a mandatory component of <i>Hirschfeldia incana</i> when the plant part is seed.</p> <p>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%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2525	HISTAMINE DIHYDROCHLORIDE	H	Only for use as an active homoeopathic ingredient.
2526	HISTIDINE	A	
2527	HISTIDINE HYDROCHLORIDE	A, E, H	
2528	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%.
2529	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2530	HOLCUS LANATUS	A, H	
2531	HOLY THISTLE HERB DRY	A, H	
2532	HOLY THISTLE HERB POWDER	A, H	
2533	HOMALOMENA OCCULTA	A, H	
2534	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 be no more than 15%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>when exposed to the sun' (or words to this effect).</p> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2535	HONEY	A, E	<p>When the route of administration is oral, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). <p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
2536	HONEY BEE	H	Only for use as an active homoeopathic ingredient.
2537	HONEY EXTRACT	E	<p>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%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p>
2538	HONEY POWDER	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>
2539	HOP STROBILE DRY	A, H	
2540	HOP STROBILE POWDER	A, H	
2541	HOPS OIL	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2542	HORDEUM DISTICHON	A, E, H	<p>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.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
2543	HORDEUM VULGARE	A, E, H	<p>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.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2544	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%.
2545	HORSE RADISH	E, H	Volatile oil components (of <i>Armoracia rusticana</i>) is a mandatory component of Horse radish. The maximum recommended daily dose must be no more than 20 mg of volatile oil components (of <i>Armoracia rusticana</i>).
2546	HOTTONIA PALUSTRIS	A, H	
2547	HOUTTUYNIA CORDATA	A, H	
2548	HOVENIA DULCIS	A, H	
2549	HUMULUS LUPULUS	A, E, H	
2550	HYALURONIC ACID	E	Only for use as an excipient in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2551	HYDNOCARPUS ANTHELMINTICA	A, H	When the medicine is for other than topical use and the plant part is seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry seed.
2552	HYDRANGEA ARBORESCENS	A, H	
2553	HYDRANGEA PANICULATA	A, H	
2554	HYDRASTIS CANADENSIS	A, E, H	
2555	HYDRATED SILICA	E	Only for use when the route of administration is other than inhalation.
2556	HYDROCHLORIC ACID	E	The concentration of the medicine must be no more than 0.5%.
2557	HYDROCOTYLE UMBELLATA	A, H	
2558	HYDROFLUORIC ACID	H	Only for use as an active homoeopathic ingredient.
2559	HYDROGEN CYANIDE	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2560	HYDROGEN PEROXIDE	A, E	<p>When used as the active ingredient, it is only for use in topical medicines for dermal application.</p> <p>The concentration of hydrogen peroxide in the medicine must be no more than 3%.</p> <p>When used as an active ingredient, can only be supplied as an un compounded medicine substance packed for retail sale and must comply with an un compounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.</p>
2561	HYDROGENATED BUTYLENE/ETHYLENE/STYRENE COPOLYMER	E	<p>Only for use in topical medicines for dermal application.</p> <p>The combined concentration of hydrogenated butylene/ethylene/styrene copolymer and hydrogenated ethylene/propylene/styrene copolymer in the medicine must be no more than 9%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2562	HYDROGENATED C6-14 OLEFIN POLYMERS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
2563	HYDROGENATED CASTOR OIL	E	
2564	HYDROGENATED COCO-GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
2565	HYDROGENATED COCONUT OIL	E	
2566	HYDROGENATED COTTONSEED OIL	E	
2567	HYDROGENATED DIMER DILINOLEYL/DIMETHYLCARBONATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			4% in the product.
2568	HYDROGENATED ETHYLENE/PROPYLENE/STYRENE COPOLYMER	E	The combined concentration of hydrogenated ethylene/propylene/styrene copolymer must be no more than 9%.
2569	HYDROGENATED LANOLIN	E	
2570	HYDROGENATED LECITHIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2571	HYDROGENATED PALM GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.6%.
2572	HYDROGENATED PALM	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	GLYCERIDES CITRATE		application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.01%.
2573	HYDROGENATED PALM KERNEL OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.2%.
2574	HYDROGENATED PALM OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. Polycyclic aromatic hydrocarbons must be kept below the level of detection.
2575	HYDROGENATED POLYDECENE	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application and not to be included in medicines intended for use in the eye.
2576	HYDROGENATED POLYISOBUTENE	E	Only for use in topical medicines for dermal application.
2577	HYDROGENATED SOYA OIL	E	
2578	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%.
2579	HYDROGENATED VEGETABLE OIL	E	
2580	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2581	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%
2582	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%
2583	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%.
2584	HYDROLYSED COLLAGEN	A, E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2585	HYDROLYSED ELASTIN	E	Only for use in topical medicines for dermal application.
2586	HYDROLYSED GELATIN	A, E	
2587	HYDROLYSED GLYCOSAMINOGLYCANS	E	Only for use in topical medicines for dermal application.
2588	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%.
2589	HYDROLYSED KERATIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2590	HYDROLYSED MAIZE STARCH	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2591	HYDROLYSED MILK PROTEIN	E	
2592	HYDROLYSED RICE	A, E, H	
2593	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%.
2594	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%.
2595	HYDROLYSED VEGETABLE PROTEIN	E	
2596	HYDROLYSED WHEAT PROTEIN	E	When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			to that effect.
2597	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%.
2598	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%.
2599	HYDROQUINONE DIMETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

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

Table 1 **Part 1**

Volume 3

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
2600	HYDROUS WOOL FAT	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2601	HYDROXOCOBALAMIN	A	
2602	HYDROXYACETOPHENONE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1%.
2603	HYDROXYAPATITE	A, E	
2604	HYDROXYCITRATE COMPLEX	A	Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			hydroxycitric acid.
2605	HYDROXYCITRIC ACID	A	
2606	HYDROXYCITRONELLAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2607	HYDROXYCITRONELLAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2608	HYDROXYCITRONELLAL-	E	Permitted for use only in combination with other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	METHYLANTHRANILATE		permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2609	HYDROXYCITRONELLOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2610	HYDROXYETHYL CETEARAMIDOPROPYLDIMONI UM CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
2611	HYDROXYETHYL UREA	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 1%.
2612	HYDROXYLATED LANOLIN	E	
2613	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%.
2614	HYDROXYLYSINE	A, E	
2615	HYDROXYMETHYLCELLULOSE	E	
2616	HYDROXYOCTACOSANYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
2617	HYDROXYPALMITOYL SPHINGANINE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			more than 0.1%.
2618	HYDROXYPROLINE	A, E	
2619	HYDROXYPROPYL DISTARCH PHOSPHATE	E	<p>Only permitted for:</p> <ul style="list-style-type: none"> - use in topical medicines for dermal application; and - medicines for internal use. <p>When for use in topical medicines for dermal application:</p> <ul style="list-style-type: none"> - not to be included medicines intended for use in the eye or damaged skin; and - the concentration of hydroxypropyl distarch phosphate in the medicine must be no more than 4%. <p>When for internal use, the maximum recommended daily dose must not contain more than 240mg of hydroxypropyl distarch phosphate.</p>
2620	HYDROXYPROPYL STARCH	E	
2621	HYDROXYPROPYLBETADEX	E	Only for use in topical medicines for dermal

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
2622	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%.
2623	HYETELLOSE	E	
2624	HYLOCEREUS LEMAIREI	E	Permitted for use only as a colour for oral and topical use.
2625	HYLOCEREUS UNDATUS	A, H	
2626	HYMETELLOSE	E	
2627	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			more than than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2628	HYOSCYAMUS LEAF POWDER	A, H	<p>Alkaloids calculated as hyoscyamine and hyoscine are mandatory components of Hyoscamus leaf powder.</p> <p>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%.</p> <p>The concentration of hyoscine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.</p>
2629	HYOSCYAMUS NIGER	A, H	<p>Alkaloids calculated as hyoscyamine and hyoscine are mandatory components of Hyoscyamus niger.</p> <p>The concentration of hyoscyamine in the medicine must be no more than 3 micrograms/kg or 3 micrograms/L or 0.3%.</p> <p>The concentration of hyoscine in the medicine must be no</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2630	HYPERICUM ASCYRON	A, H	
2631	HYPERICUM JAPONICUM	A, H	
2632	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.'
2633	HYPROLOSE	E	
2634	HYPROMELLOSE	E	
2635	HYPROMELLOSE PHTHALATE	E	
2636	HYPTIS SUAVEOLENS	A, H	
2637	HYSSOPUS OFFICINALIS	A, E, H	
2638	IBERIS AMARA	A, H	
2639	ICHTHAMMOL	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2640	ILEX AQUIFOLIUM	A, H	
2641	ILEX CHINENSIS	A, H	
2642	ILEX PARAGUARIENSIS	A, E, H	<p>Caffeine is a mandatory component of Ilex paraguariensis.</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFFR) ‘The recommended dose of this medicine provides small amounts of caffeine.’</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFF) ‘Contains caffeine [state quantity per dosage unit or per mL or per gram of product]’.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2643	ILEX ROTUNDA	A, H	
2644	ILEX VERTICILLATA	A, H	
2645	ILLICIAM VERUM	A, H	<p>When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 50 millilitres.</p> <p>When the concentration of Illicium verum oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning</p> <p>statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
2646	IMIDUREA	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2647	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%.
2648	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%.
2649	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%.
2650	IMPATIENS BALSAMINA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2651	IMPATIENS GLANDULIFERA	A, H	
2652	IMPERATA CYLINDRICA	A, E, H	
2653	INDIGO CARMINE	E	Permitted for use only as a colour for oral and topical use.
2654	INDIGO CARMINE ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
2655	INDIGOFERA TINCTORIA	A, H	
2656	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%.
2657	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.
2658	INDOLENE	E	Permitted for use only in combination with other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2659	INDUSTRIAL METHYLATED SPIRIT	E	
2660	INOSITOL	A, E	
2661	INULA BRITANNICA	A, H	
2662	INULA HELENIUM	A, E, H	
2663	INULA RACEMOSA	A, H	
2664	INULIN	A, E	
2665	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%.
2666	INVERT SUGAR	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar,

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
2667	INVERT SYRUP	E	<p>Glucose is a mandatory component of Invert syrup when the route of administration is oral or sublingual.</p> <p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
2668	IODINE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>Only for external use when the concentration of 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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2669	IODOPROPYNYL BUTYLCARBAMATE	E	For use as an excipient ingredient in topical medicines only. The concentration in aqueous medicines must be no more than 10%.
2670	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%.
2671	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
2672	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%.
2673	IPECACUANHA POWDER	A, H	Emetine is a mandatory component of Ipecacuanha Powder. The concentration of emetine in the medicine must be no more than 0.2%.
2674	IPECACUANHA PREPARED	A, H	Emetine is a mandatory component of Ipecacuanha Prepared. The concentration of emetine in the medicine must be no more than 0.2%.
2675	IPECACUANHA ROOT LIQUID EXTRACT	A, H	Emetine is a mandatory component of Ipecacuanha root liquid extract. The concentration of emetine in the medicine must be no

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			more than 0.2%.
2676	IPOMOEA BATATAS	A, H	
2677	IPOMOEA JALAPA	A, H	
2678	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>
2679	IRIS DOMESTICA	A, H	
2680	IRIS FLORENTINA	A, H	
2681	IRIS GERMANICA	A, H	
2682	IRIS PALLIDA	A, H	
2683	IRIS TENAX	H	
2684	IRIS VERSICOLOR	A, H	
2685	IRON	A, H	Only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<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 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2686	IRON (II) BISGLYCINE SULFATE	A	Only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	TRIHYDRATE		<p>Iron is a mandatory component of iron (II) bisglycine sulfate trihydrate.</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>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2687	IRON (II) GLYCINATE	A	<p>Only for use in oral medicines.</p> <p>Iron is a mandatory component of iron (II) glycinate.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<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>When for internal use except for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register on or after 1 October 2017 the medicine</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>must have the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2688	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>claims and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>
2689	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</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 and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2690	IRON OXIDE BLACK	E	<p>Permitted for use only as a colour for oral and topical use.</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>
2691	IRON OXIDE RED	E	<p>Permitted for use only as a colour for oral and topical use.</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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2692	IRON OXIDE YELLOW	E	<p>Permitted for use only as a colour for oral and topical use.</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>
2693	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 of iron.</p> <p>In undivided preparations, the primary pack must contain no more than 750 mg of iron</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>(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 and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statement on the medicine label:</p> <p>- (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).</p> <p>When for internal use except</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for iron-containing multivitamin/mineral products indicated for general nutritional support that do not make specific iron-deficiency related claims and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statement on the medicine label if supplied after 1 April 2019: - (IRONDEF) 'Not for the treatment of iron deficiency conditions' (or words to that effect).
2694	IRONE	E	
2695	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%.
2696	ISATIS TINCTORIA	A, H	
2697	ISOAMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
2698	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>
2699	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2700	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>
2701	ISOAMYL BENZOATE	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>
2702	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</p>

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

Table 1 **Part 1**

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
2703	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>
2704	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2705	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%.
2706	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%.
2707	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2708	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%.
2709	ISOAMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2710	ISOAMYL LAURATE	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
2711	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 be no more than 10%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). <p>When used in primary sunscreen products and listed in the Register before 1</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2712	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 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>
2713	ISOAMYL PHENYLETHYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
2714	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%.
2715	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2716	ISOBERGAMIATE	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>
2717	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>
2718	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2719	ISOBORNYL CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2720	ISOBUTANE	E	Only for use in topical medicines for dermal application.
2721	ISOBUTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2722	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.
2723	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%.
2724	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%.
2725	ISOBUTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.
2726	ISOBUTYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2727	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%.
2728	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2729	ISOBUTYL HYDROXYBENZOATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:</p> <p>- (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.</p>
2730	ISOBUTYL ISOBUTYRATE	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2731	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%.
2732	ISOBUTYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2733	ISOBUTYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2734	ISOBUTYL QUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2735	ISOBUTYL SALICYLATE	E	Only for use in topical medicines for dermal application.
2736	ISOBUTYLENE/ISOPRENE COPOLYMER	E	Only for oral use when the dosage form is chewing gum. The concentration must be consistent with best practice for the production of gum delivery systems.
2737	ISOBUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2738	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%.
2739	ISOCETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2740	ISOCETYL LINOLEOYL STEARATE	E	Only for use in topical medicines for dermal application.
2741	ISOCETYL STEARATE	E	Only for use in topical medicines for dermal application.
2742	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration must be no more than 10%.
2743	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%.
2744	ISODECYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
2745	ISODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2746	ISODECYL OLEATE	E	Only for use in topical medicines for dermal application.
2747	ISODECYL SALICYLATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			intended for use in the eye. The concentration must be no more than 2%.
2748	ISODODECANE	E	Only for use in topical medicines for dermal application.
2749	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%.
2750	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2751	ISOEUGENYL 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	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>
2753	ISOHEXADECANE	E	Only for use in topical medicines for dermal application.
2754	ISOJASMONE	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 than 1%.</p>
2755	ISOLEUCINE	A, E	
2756	ISOMALT	E	<p>When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGOLS) ‘Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect]’.</p>
2757	ISOMENTHONE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
2758	ISOMETHYLIONONE	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>
2759	ISONONYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2760	ISONONYL ISONONANOATE	E	<p>Only for use in topical medicines for dermal application and not to be</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 15%.
2761	ISOPENTANE	E	For dental use only. The concentration must be no more than 2%.
2762	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%.
2763	ISOPHORONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
2764	ISOPHYTOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2765	ISOPROPYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2766	ISOPROPYL 4-HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:</p> <p>- (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved name of hydroxybenzoate used]’ (or words to this effect) if product contains one hydroxybenzoate source.</p>
2767	ISOPROPYL ACETATE	E	Only for use in topical medicines for dermal application.
2768	ISOPROPYL ALCOHOL	E	
2769	ISOPROPYL 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>
2770	ISOPROPYL CINNAMATE	E	Permitted for use only in

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2771	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
2772	ISOPROPYL LANOLATE	E	Only for use in topical medicines for dermal application.
2773	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%.
2774	ISOPROPYL MYRISTATE	E	
2775	ISOPROPYL PALMITATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2776	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%.
2777	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2778	ISOPROPYL TITANIUM TRIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 0.2%.
2779	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2780	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%.
2781	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%.
2782	ISOSTEARIC ACID	E	Only for use in topical medicines for dermal application.
2783	ISOSTEAROYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye. The concentration must be no more than 0.3%.
2784	ISOSTEARYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2785	ISOSTEARYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2786	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%.
2787	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2788	ISOVALERALDEHYDE	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>
2789	ISOVALERIC ACID	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>
2790	ISPAGHULA HUSK DRY	A, H	<p>When a dose for children is stated, the medicine requires the following warning statement on the medicine label:</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (PSYLL) 'On medical advice' (or words to that effect).
2791	ISPAGHULA HUSK POWDER	A, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
2792	IVA AXILLARIS	A, H	
2793	JAMAICA DOGWOOD BARK DRY	A, H	
2794	JAMAICA DOGWOOD BARK POWDER	A, H	
2795	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%.

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

Table 1 **Part 1**

Volume 3

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2796	JASMINE LACTONE	E	Only for use in topical medicines for dermal application.
2797	JASMINE OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2798	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%.
2799	JASMINUM OFFICINALE	A, E, H	
2800	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
2801	JATEORHIZA PALMATA	A, H	
2802	JATROPHA CURCAS	H	Only for use as an active homoeopathic ingredient
2803	JERUSALEM ARTICHOKE	E	
2804	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%.
2805	JUGLANS CINEREA	A, E, H	
2806	JUGLANS NIGRA	A, E, H	
2807	JUGLANS REGIA	A, H	
2808	JUNCUS EFFUSUS	A, H	
2809	JUNIPER BERRY OIL	A, E, H	
2810	JUNIPER BERRY OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2811	JUNIPERUS CALIFORNICA	A, H	
2812	JUNIPERUS COMMUNIS	A, E, H	
2813	JUNIPERUS MEXICANA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2814	JUNIPERUS OXYCEDRUS	A, H	
2815	JUNIPERUS VIRGINIANA	A, E, H	
2816	JUSTICIA ADHATODA	A, H	

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

Schedule 1

Table 1 **Part 1**

Volume 3