



Therapeutic Goods (Permissible Ingredients) Determination No. 3 of 2018

made under subsection 26BB(1) of the

Therapeutic Goods Act 1989

I, Michael Shum, a delegate of the Minister for Health for the purposes of subsection 26BB(1) of the *Therapeutic Goods Act 1989* (the Act), **HEREBY**:

- (a) Repeal the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018; and
- (b) Make the following determination specifying:
 - (i) ingredients for the purposes of paragraph 26BB(1)(a) of the Act; and
 - (ii) requirements applying to those ingredients for the purposes of paragraph 26BB(1)(b) of the Act.

Dated this 21 September 2018

(Signed by)

Michael Shum

Delegate of the Minister for Health

1 Name of Determination

This Determination is the *Therapeutic Goods (Permissible Ingredients) Determination No. 3 of 2018*.

2 Commencement

This Determination commences on 28 September 2018.

3 Interpretation

In this Determination:

Act means the *Therapeutic Goods Act 1989*.

Code Tables are tables that can be accessed from the Therapeutic Goods Administration Business Service website at www.ebs.tga.gov.au under the heading “Public TGA Information”.

European Pharmacopoeia is as defined under the Act.

Mandatory component is a naturally occurring constituent in a specified ingredient listed in column 2 of Table 1 of Schedule 1 to this Determination.

4 Permissible ingredients and requirements applying to those ingredients

Permissible ingredients and requirements applying to those ingredients under Table 1

- (1) The ingredients specified in column 2 of Table 1 in Part 2 of Schedule 1 (Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine) to this Determination (Schedule 1) are specified for the purposes of paragraph 26BB(1)(a) of the Act.
- (2) Subject to subsection (3), for the purposes of paragraph 26BB(1)(b) of the Act, the ingredients specified in column 2 of Table 1 in Part 2 of Schedule 1 are subject to the following requirements:
 - (a) they may only be used in a medicine for a purpose or purposes specified in column 3 of Table 1 in Part 2 of Schedule 1; and
 - (b) they must comply with the requirements set out in column 4 of Table 1 in Part 2 of Schedule 1.
- (3) The requirements set out in column 4 in relation to a mandatory component of an ingredient listed in column 2 of Table 1 in Part 2 of Schedule 1 apply to that specified ingredient.

Indications and Product Warning Acronyms based on the electronic Code Table document

- (4) The acronyms in column 4 of Table 1 in Part 2 of Schedule 1 in closed brackets that are associated with warning statements in relation to particular ingredients specified in column 2 of Table 1 in Part 2 of Schedule 1, are acronyms from the

Code Tables under the headings “Indications” or “Product Warning” and are not required to be included on the label of the medicine.

Note: Examples of these acronyms are:

(CHILD3), (PREGNT), (GLUTEN), (PEANUT) and (ARGIN1).

Additional requirements applying to specified ingredients in Table 1 that are derived from animal origins

- (5) Ingredients specified in column 2 of Table 1 in Part 2 of Schedule 1 that are derived from animal origins (non-human) must also comply with the following requirements, for the purposes of paragraph 26BB(1)(b) of the Act:
- (a) a certification must be obtained under subsection 26A(4A) of the Act from the Secretary, prior to an application being made for the listing in the Australian Register of Therapeutic Goods, under section 26A of the Act, of a medicine that contains the ingredient, that the Secretary is satisfied of the safety of the ingredient;
 - (b) the safety of the ingredient must have been assessed against the principles and requirements detailed in the European Pharmacopoeia general monograph 1483: *Products with risk of transmitting agents of animal spongiform encephalopathies*, including General Text 5.2.8: *Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products*.

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

(section 4)

Part 1—Interpretation of Table 1

Definitions

At Table 1:

“**A**” means an active ingredient.

Act means the *Therapeutic Goods Act 1989*.

Active ingredient is as defined in the Regulations.

British Pharmacopoeia is as defined under the Act.

“**E**” means an excipient.

Excipient means an ingredient that is not an active ingredient or a homoeopathic preparation ingredient.

Note: An excipient includes an ingredient that provides flavour, fragrance or colour to the medicine.

“**H**” means a homoeopathic preparation ingredient.

Homoeopathic preparation ingredient means an ingredient that is a constituent of a preparation that is:

- (a) formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate; and
- (b) prepared according to the practices of homoeopathic pharmacy using the methods of:
 - (i) serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or
 - (ii) serial trituration in lactose.

Mother tincture is as defined in the Regulations.

Regulations means the Therapeutic Goods Regulations 1990.

United States Pharmacopoeia-National Formulary is as defined under the Act.

Part 2 – 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
1	(1,7,7-TRIMETHYLBICYCLO(2.2.1)HEPT-2-YL)-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%.
2	(1R,2S,5R)-N-(4-METHOXYPHENYL)-5-METHYL-2-(1-METHYLETHYL)CYCLOHEXANECARBOXAMIDE	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%.
3	(5E)-3-METHYL-5-CYCLOTETRADECEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.

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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
4	(5Z)-3-METHYL-5-CYCLOTETRADECEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
5	(E)-2-(3,5-DIMETHYLHEX-3-EN-2-YLOXY)-2-METHYLPROPYL CYCLOPROPANECARBOXYLATE	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%.
6	(E)-3-METHYLCYCLOPENTADEC-5-EN-1-ONE	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%.
7	(E, E)-2,6-NONADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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
			<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>
8	(S)-LACTIC ACID	A, E, H	
9	(S)-S-ADENOSYLMETHIONINE DISULFATE DITOSYLATE DIHYDRATE	A	<p>(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate ditosylate dihydrate.</p> <p>(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
10	(S)-S-ADENOSYLMETHIONINE DISULFATE TOSYLATE	A	<p>(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tosylate.</p> <p>(S)-S-Adenosylmethionine in</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>the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
11	(S)-S-ADENOSYLMETHIONINE DISULFATE TRITOSYLATE DIHYDRATE	A	<p>(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tritosylate dihydrate.</p> <p>(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
12	(S)-S-ADENOSYLMETHIONINE	A	(S)-S-Adenosylmethionine is a mandatory component of (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
	HEXASULFATE DIHYDRATE		<p>S-Adenosylmethionine hexasulfate dihydrate.</p> <p>(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
13	(S)-S-ADENOSYLMETHIONINE HEXATOSYLATE DIHYDRATE	A	<p>(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine hexatosylate dihydrate and must be declared in the application.</p> <p>(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that</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
			effect)'
14	(S)-S-ADENOSYLMETHIONINE PENTASULFATE DIHYDRATE	A	<p>(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine pentasulfate dihydrate.</p> <p>(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>-(SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
15	(S)-S-ADENOSYLMETHIONINE PENTATOSYLATE DIHYDRATE	A	<p>(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine pentatosylate dihydrate.</p> <p>(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from</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
			bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
16	(S)-S-ADENOSYLMETHIONINE TETRASULFATE DIHYDRATE	A	<p>(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine tetrasulfate dihydrate.</p> <p>(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
17	(S)-S-ADENOSYLMETHIONINE TETRATOSYLATE DIHYDRATE	A	<p>(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine tetratosylate dihydrate.</p> <p>(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on 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
			label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
18	(S)-S-ADENOSYLMETHIONINE TRISULFATE DITOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine trisulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
19	(Z)-HEX-3-ENYL 2-ETHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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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
			flavour concentration in a medicine must be no more than 5%.
20	(Z, Z)-3,6-NONADIEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
21	(±)-NARINGENIN	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%.
22	1,1,1-TRICHLOROETHANE	E	The concentration in the medicine must be no more than 25%.
23	1,2-HEXANEDIOL	E	Only for use 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 products intended for use in the eye. The concentration in the medicine must be no more than 1%.
24	1,3,4,6,7,8A-HEXAHYDRO-1,1,5,5-TETRAMETHYL-2H-2,4A-METHANONAPHTHALEN-8(5H)-ONE	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%.
25	1,3,5-UNDECATRIENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
26	1,3-BUTYLENE GLYCOL	E	
27	1,3-NONANEDIOL ACETATE, MIXED ESTERS	E	Permitted for use only in combination with other permitted ingredients as a

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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
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
28	1,3-NONANEDIOL, DIACETATE	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%.
29	1,4-CINEOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%
30	1,4-DIOXACYCLOHEXADECANE-	E	Permitted for use only in combination with other

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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
	5,16-DIONE		permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
31	1,5,9-TRIMETHYL-13-OXABICYCLO[10.1.0]TRIDECA-4,8-DIENE	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%.
32	1,7,7-TRIMETHYLBICYCLO[4.4.0]DECAN-3-YL 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%.
33	1-(2,2,6-TRIMETHYLCYCLOHEXYL)-3-HEXANOL	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%.
34	1-(2,6,6-TRIMETHYL-2-CYCLOHEXEN-1-YL)-1-PENTEN-3-ONE	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%.
35	1-(3,3-DIMETHYLCYCLOHEXYL)ETHYL FORMATE	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%.
36	1-(4-ISOPROPYLCYCLOHEXYL)ETHANOL	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%.
37	1-(5,5-DIMETHYL-1-CYCLOHEXEN-1-YL)-4-PENTEN-	E	Permitted for use only in combination with other permitted ingredients as a

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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
	1-ONE		fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
38	1-DODECANOL	E	Permitted for use: (a) only in combination with other permitted ingredients as a flavour; and (b) in topical medicines for dermal application. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
39	1-HEPTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
40	1-HEXEN-3-OL	E	Permitted for use only in combination with other

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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
			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
41	1-METHOXY-4-PROPENYLBENZENE	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%.
42	1-METHYL-2-[(1,2,2-TRIMETHYLBICYCLO[3.1.0]HEX-3-YL)METHYL]-CYCLOPROPANEMETHANOL	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%.
43	1-METHYL-3-(2-METHYLPROPYL)-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

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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
			1%.
44	1-METHYL-4-(4-METHYL-3-PENTENYL)-3-CYCLOHEXENE-1-CARBOXALDEHYDE	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%.
45	1-OCTEN-3-ONE	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%.
46	1-P-MENTHENE-8-THIOL	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%.
47	1-PENTEN-3-OL	E	Permitted for use only in combination with other permitted ingredients as a

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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
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
48	10-UNDECEN-1-OL	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%.
49	10-UNDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
50	16-HYDROXY-12-OXAHEXADECANOIC ACID, OMEGA-LACTONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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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
			fragrance concentration in a medicine must be no more than 1%.
51	2,2,3-TRIMETHYLCYCLOPENT-3-ENE-1-ETHYL 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%.
52	2,2,5-TRIMETHYL-5-PENTYLCYCLOPENTANONE	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%.
53	2,2-DIMETHYL-3-(3-METHYL-2,4-PENTADIENYL)-OXIRANE	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
54	2,2-DIMETHYL-3-PHENYLPROPANOLL	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%.
55	2,2-DIMETHYL-5-(1-METHYLPROPEN-1-YL) TETRAHYDROFURAN	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%.
56	2,2-DIMETHYL-P-ETHYLPHENYL-PROPANENITRILE	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%.
57	2,3,4-TRIMETHYL-3-PENTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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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
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
58	2,3,5,6-TETRAMETHYLPYRAZINE	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%.
59	2,3,5-TRIMETHYLPYRAZINE	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%.
60	2,3-DIETHYLPYRAZINE	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%.

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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
61	2,3-DIHYDRO-1,1-DIMETHYL-1H-INDENE-AR-PROPANAL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient. The total fragrance proprietary excipient formulation concentration in a medicine must not be more than 1%.
62	2,3-DIHYDRO-2,5-DIMETHYL-1H-INDENE-2-METHANOL	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%.
63	2,3-DIMETHYLPYRAZINE	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%.
64	2,3-HEXADIONE	E	Permitted for use only in combination with other permitted ingredients as a

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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
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
65	2,3-HEXANEDIONE	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%.
66	2,3-PENTANEDIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
67	2,4,5-TRIMETHYLTHIAZOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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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
			flavour concentration in a medicine must be no more than 5%.
68	2,4,6-TRIMETHYL-4-PHENYL-1,3-DIOXANE	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%.
69	2,4-DECADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 3 mg of 2,4-Decadienal.
70	2,4-DIMETHYL BUTADIENEACROLEIN	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
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
71	2,4-DIMETHYL THIAZOLE	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%.
72	2,4-DIMETHYL-3-CYCLOHEXENE CARBOXALDEHYDE	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%.
73	2,4-DIMETHYL-4,4A,5,9B-TETRAHYDROINDENO[1,2-D]-1,3-DIOXIN	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
74	2,4-DIMETHYL-4-PHENYL TETRAHYDROFURAN	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%.
75	2,4-HEPTADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 3 mg of 2,4-Heptadienal.
76	2,4-HEXADIENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour 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
			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.</p> <p>The maximum daily dose must provide no more than 13.5 mg of 2,4-Hexadienol.</p>
77	2,5-DIETHYLTETRAHYDROFURAN	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>
78	2,5-DIMETHYL-2-OCTEN-6-ONE	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>
79	2,5-DIMETHYL-4-HYDROXY-3(2H)-FURANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or fragrance.</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>If used in a flavour the total flavour concentration in the 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 than 1%.</p>
80	2,5-DIMETHYL-4-METHOXY-3(2H)-FURANONE	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>
81	2,5-DIMETHYLPYRAZINE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance, or a printing ink.</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> <p>If used in a printing ink the total printing ink concentration in a medicine must be no more</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
			than 0.1%
82	2,6,6,TRIMETHYL-2-CYCLOHEXENE-1,4-DIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
83	2,6,9,10-TETRAMETHYL-1-OXASPIRO(4.5)DECA-3,6-DIENE	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%.
84	2,6-DIMETHOXYPHENOL	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

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

Table 1 **Part 2**

Volume 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
			5%.
85	2,6-DIMETHYL HEPTAN-2-OL	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%.
86	2,6-DIMETHYL-2-HEPTENAL-(7)	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
87	2,6-DIMETHYL-3,5-OCTADIEN-2-OL	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
88	2,6-DIMETHYL-4-HEPTYL 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%.
89	2,6-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
90	2,6-NONADIEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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%.
91	2,6-OCTADIENOIC ACID, 3,7-DIMETHYL-, METHYL ESTER, (2E)-	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%.
92	2-(1,1-DIMETHYLETHYL)-1,4-DIMETHOXY-BENZENE	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%.
93	2-(2-(4-METHYL-3-CYCLOHEXEN-1-YL)PROPYL)CYCLOPENTANONE	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%.
94	2-(2-METHYLPHENYL)ETHANOL	E	Permitted for use only 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 fragrance proprietary excipient formulation.</p> <p>The ingredient is not to be included in medicines intended for use in the eye.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
95	2-[(3,7-DIMETHYL-6-OCTEN-1-YLIDENE)AMINO]BENZOIC ACID, METHYL ESTER	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>
96	2-[1-(3,3-DIMETHYLCYCLOHEXYL)ETHOXY]-2-METHYLPROPYL]CYCLOPROPANECARBOXYLATE	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>
97	2-[1-(3,3-DIMETHYLCYCLOHEXYL)ETHOXY]-2-OXOETHYL PROPANOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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

Table 1 **Part 2**

Volume 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
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
98	2-ACETYLFURAN	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%.
99	2-ACETYLPYRAZINE	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%.
100	2-ACETYLPYRIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If 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%.
101	2-AMINO-2-METHYL-1-PROPANOL	E	Only for use in topical medicines for dermal application.
102	2-BENZYL-4,4,6-TRIMETHYL-1,3-DIOXANE	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%.
103	2-BUTEN-1-OL	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%.
104	2-BUTYL-4,4,6-TRIMETHYL-1,3-DIOXANE	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%.
105	2-CYCLOHEXYLIDENE-2-O-TOLYL-ACETONITRILE	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%.
106	2-DECENAL	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%.
107	2-DODECANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. 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 1%.
108	2-DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
109	2-ETHOXY-4-(METHOXYMETHYL)-PHENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
110	2-ETHOXYETHANOL	E	The residual solvent limit for 2-Ethoxyethanol is 1.6 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.016%.

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
111	2-ETHYL-1-HEXANOL	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%.
112	2-ETHYL-3,5-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
113	2-ETHYL-3,6-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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
114	2-ETHYL-3-METHYLPYRAZINE	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%.
115	2-ETHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-2-BUTEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
116	2-ETHYL-4-HYDROXY-5-METHYL-3(2H)-FURANONE	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%.

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

Table 1 **Part 2**

Volume 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
117	2-ETHYL-4-METHYLTHIAZOLE	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%.
118	2-ETHYL-ALPHA,ALPHA-DIMETHYL-BENZENEPROPANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
119	2-ETHYLBUTYRIC ACID	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%.
120	2-HEPTANOL	E	Permitted for use only in combination with other

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

Table 1 **Part 2**

Volume 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
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
121	2-HEPTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
122	2-HEPTYL CYCLOPENTANONE	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%.
123	2-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
			<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>
124	2-HYDROXYACETOPHENONE	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 1%.</p>
125	2-ISOBUTYL-3-METHOXPYRAZINE	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>
126	2-ISOBUTYL-4-METHYLTETRAHYDRO-2H-PYRAN-4-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total</p>

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

Table 1 **Part 2**

Volume 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
			fragrance concentration in a medicine must be no more than 1%.
127	2-ISOPROPOXYETHYL 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%.
128	2-ISOPROPYL-4-METHYLTHIAZOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
129	2-MERCAPTOPROPIONIC ACID	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%.
130	2-METHOXY-3- SECBUTYLPYRAZINE	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%.
131	2-METHOXY-4-VINYLPHENOL	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%.
132	2-METHYL BUTYRIC 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%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
133	2-METHYL HEPTANOIC ACID	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%.
134	2-METHYL-2-PENTENOIC ACID	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%.
135	2-METHYL-2-VINYL-5-ISOPROPENYL TETRAHYDROFURAN	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%.
136	2-METHYL-3-(3,4-METHYLENEDIOXYPHENYL)PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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
			<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>
137	2-METHYL-3-(4-METHOXYPHENYL)PROPANAL	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>
138	2-METHYL-3-[4-(2-METHYLPROPYL)PHENYL]PROPANAL	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>
139	2-METHYL-3-BUTEN-2-OL	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</p>

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

Table 1 **Part 2**

Volume 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
			medicine must be no more than 5%.
140	2-METHYL-3-FURANTHIOL	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%.
141	2-METHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)BUTANOL	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%.
142	2-METHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTENYL)-2-BUTEN-1-OL	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%. 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
143	2-METHYL-4-(2,6,6-TRIMETHYL-1-CYCLOHEXEN-1-YL)-2-BUTENAL	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%.
144	2-METHYL-4-(CAMPHENYL-8)-CYCLOHEXANONE	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%.
145	2-METHYL-4-PROPYL-1,3-OXTHIANE	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%.
146	2-METHYL-5-(METHYLTHIO)FURAN	E	Permitted for use only in combination with other permitted ingredients as a

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
147	2-METHYL-5-PHENYLPENTANOL	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%.
148	2-METHYLBUTYL 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%.
149	2-METHYLBUTYL 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%.

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
150	2-METHYLBUTYL PHENYLETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
151	2-METHYLBUTYL 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%.
152	2-METHYLHEXANOIC ACID	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%.
153	2-METHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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
			<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>
154	2-METHYLTETRAHYDROFURAN-3-ONE	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>
155	2-METHYLUNDECANAL	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>
156	2-METHYLVALERIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
157	2-NONENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
158	2-NONENENITRILE	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%.
159	2-OXOBUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
			flavour concentration in a medicine must be no more than 5%.
160	2-PENTADECANONE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
161	2-PENTANOL	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%.
162	2-PENTANONE	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%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
163	2-PENTENAL	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%.
164	2-PENTYL FURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
165	2-PHENYLPROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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
166	2-PHENYLPROPIONALDEHYDE 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%.
167	2-PROPENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
168	2-SEC-BUTYL CYCLOHEXANONE	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%.

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

Table 1 **Part 2**

Volume 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
169	2-TERT-BUTYLCYCLOHEXANOL	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%.
170	2-TERT-BUTYLCYCLOHEXYLOXY-2-BUTANOL	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%.
171	2-TRANS-6-CIS-NONADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
172	2-TRIDECANONE	E	Permitted for use only in combination with other

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
			<p>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 than 1%.</p>
173	2-TRIDECENAL	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>
174	2-TRIDECENENITRILE	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>

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

Table 1 **Part 2**

Volume 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
175	2-UNDECENAL	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%.
176	3,3-DIMETHYL-5-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-4-PENTEN-2-OL	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%.
177	3,3-DIMETHYLACRYLIC ACID	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%.
178	3,4,4A,5,8,8A-HEXAHYDRO-3',7-DIMETHYLSPIRO-1,4-METHANONAPHALENE-2(1H),2'-OXIRANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. 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 than 1%.
179	3,4-DIMETHYL-1,2-CYCLOPENTADIONE	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%.
180	3,5,5-TRIMETHYL HEXANAL	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%.
181	3,5,5-TRIMETHYLHEXYL 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%.

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
182	3,5,6,6-TETRAMETHYL-4-METHYLENEHEPTAN-2-ONE	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%.
183	3,5-DIMETHOXYTOLUENE	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%.
184	3,5-DIMETHYL-3-CYCLOHEXENE-1-CARBOXALDEHYDE	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%.
185	3,6-DIMETHYL-3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. 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 2**

Volume 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
			fragrance concentration in a medicine must be no more than 1%.
186	3,7-DIMETHYL OCTANAL	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%.
187	3,7-DIMETHYL-1-OCTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
188	3,7-DIMETHYL-2,6-NONADIENENITRILE	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%.
189	3,7-DIMETHYL-7-METHOXYOCTAN-2-OL	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%.
190	3-(3-ISOPROPYLPHENYL)BUTANAL	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%.
191	3-(4-ETHYLPHENYL)-2,2-DIMETHYLPROPANAL	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%.
192	3-(4-HYDROXYPHENYL)-1-(2,4,6-TRIHYDROXYPHENYL)-1-	E	Permitted for use only in combination with other permitted ingredients as a

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

Table 1 **Part 2**

Volume 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
	PROPANONE		flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
193	3-(4-TERT-BUTYLPHENYL)-PROPANAL	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%.
194	3-(ISO-CAMPHYL-5)-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%.
195	3-(METHYLTHIO)-1-HEXYL 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%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
196	3-CARENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
197	3-DODECENAL	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%.
198	3-ETHYLPYRIDINE	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%.

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

Table 1 **Part 2**

Volume 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
199	3-HEPTYLDIHYDRO-5-METHYL-2(3H)-FURANONE	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%.
200	3-HEXANONE	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%.
201	3-HEXEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
202	3-ISO-CAMPHYL-5-CYCLOHEXAN-1-OL	E	Permitted for use only in combination with other

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

Table 1 **Part 2**

Volume 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
			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
203	3-METHYL THIOPROPIONALDEHYDE ETHANOL	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%.
204	3-METHYL-2- (PENTYLOXY)CYCLOPENT-2- EN-1-ONE	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%.
205	3-METHYL-5-(2,2,3-TRIMETHYL- 3-CYCLOPENTEN-1-YL)-4- PENTEN-2-OL	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

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

Table 1 **Part 2**

Volume 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
			1%.
206	3-METHYL-5-PHENYL PENT-2-ENENITRILE	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%.
207	3-METHYL-5-PHENYLPENTANAL	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%.
208	3-METHYL-5-PHENYLPENTANENITRILE	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%.
209	3-METHYL-5-PHENYLPENTANOL	E	Permitted for use only in combination with other permitted ingredients as a

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

Table 1 **Part 2**

Volume 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
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
210	3-METHYL-5-PROPYL-2-CYCLOHEXEN-1-ONE	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%.
211	3-METHYLCYCLOPENTADECANO NE	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%.
212	3-METHYLCYCLOPENTADECENO NE	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
213	3-METHYLTHIOHEXANOL	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%.
214	3-OCTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
215	3-OCTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation 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
216	3-PENTYLTETRAHYDRO-2H-PYRAN-4-OL 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%.
217	3-PHENYLPROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
218	3-PHENYLPROPYL 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
219	3-PHENYLPROPYL 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%.
220	3-PROPYLIDENE PHTHALIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
221	3-TRANS-ISOCAMPHYLCYCLOHEXANOL	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%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
222	3A,6,6,9A-TETRAMETHYLDODECAHYDRO NAPHTHO[2,1-B] FURAN	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%.
223	4,4A,5,9B-TETRAHYDRO-2,4-DIMETHYL-INDENO(1,2-D)-1,3-DIOXIN	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%.
224	4,4A,5,9B-TETRAHYDROINDENO(1,2-D)-1,3-DIOXIN	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%.
225	4,5-DIMETHYL-3-HYDROXY-2(5H)FURANONE	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%.
226	4,7-METHANO-1H-INDENEMETHANOL, OCTAHYDRO-, ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
227	4,7-METHANO-3A,4,5,6,7,7A-HEXAHYDRO-5 (OR 6) - INDENYL 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%.
228	4,8-DIMETHYL-3,7-NONADIEN-2-OL	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
229	4-(4-HYDROXY-4-METHYLPENTYL)-3-CYCLOHEXENE CARBOXALDEHYDE	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%.
230	4-(4-METHYL-3-PENTEN-1-YL)-3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
231	4-(5,5,6-TRIMETHYLBICYCLO(2.2.1)HEPT-2-YL)-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%.

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
232	4-(METHYLTHIO)-4-METHYL-2-PENTANONE	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%.
233	4-(PARA-HYDROXYPHENYL)-2-BUTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
234	4-(PARA-METHOXYPHENYL)-2-BUTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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
235	4-ACETYL-6-TERTIARY-BUTYL-1,1-DIMETHYLINDAN	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%.
236	4-ETHYL GUAIACOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
237	4-HEPTANONE	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%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
238	4-HYDROXYBENZALDEHYDE	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%.
239	4-HYDROXYBENZYL 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%.
240	4-ISOPROPYL-3-METHYLPHENOL	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%.
241	4-METHOXY-2-METHYL-2-BUTANETHIOL	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%.
242	4-METHYL-3-DECEN-5-OL	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%.
243	4-METHYL-4-MERCAPTOPENTAN-2-ONE	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%.
244	4-METHYL-4-PHENYL-2-PENTYL 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%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
245	4-METHYL-5-THIAZOLETHANOL	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>
246	4-METHYLBENZYLIDENE CAMPHOR	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 4%.</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

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>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).
247	4-METHYLPENTANOIC ACID	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>
248	4-METHYLPHENYL OCTANOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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%.
249	4-PARA METHOXYPHENYL-3-BUTANONE	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%.
250	4-PENTENOIC ACID	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%.
251	4-TERT-BUTYL-2,6-DIMETHYL ACETOPHENONE	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
252	4-TERT-BUTYLCYCLOHEXANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
253	4-TERT-PENTYLCYCLOHEXANONE	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%.
254	5,6,7,8-TETRAHYDROQUINOXALINE	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%.
255	5,7-DIHYDRO-2-METHYLTHIENO (3,4D) PYRIMIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
256	5-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-3-METHYLPENTAN-2-OL	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%.
257	5-ACETYL-1,1,2,3,3,6-HEXAMETHYL INDAN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
258	5-CYCLOHEXADECEN-1-ONE	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

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

Table 1 **Part 2**

Volume 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
			medicine must be no more than 1%.
259	5-ETHYL-3-HYDOXY-4-METHYL-2(5H)-FURANONE	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%.
260	5-ETHYL-4-HYDROXY-2-METHYL-3(2H)-FURANONE	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%.
261	5-HYDROXY-4-METHYLHEXANOIC ACID DELTA-LACTONE	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%.
262	5-METHOXYPSORALEN	E	Permitted for use only in combination with other

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

Table 1 **Part 2**

Volume 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
			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
263	5-METHYL 2-PHENYL HEXEN-2-AL	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%.
264	5-METHYL-2-THIOPHENE CARBOXALDEHYDE	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%.
265	5-METHYL-3-BUTYL TETRAHYDRO PYRAN-4-YL 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

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%.
266	5-METHYL-3-HEPTANONE OXIME	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%.
267	5-PENTYL-2(5H)-FURANONE	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%.
268	6,6-DIMETHOXY-2,5,5-TRIMETHYL-2-HEXENE	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%.
269	6,6-DIMETHYL-2-NORPINENEPROPIONALDEHYD	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
	E		fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
270	6,7-DIHYDRO-1,1,2,3,3-PENTAMETHYL-4(5H)-INDANONE	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%.
271	6-BUTYL-3,6-DIHYDRO-2,4-DIMETHYL-2H-PYRAN	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%.
272	6-METHOXY-2,6-DIMETHYLHEPTAN-1-AL	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%.
273	6-METHOXYDICYCLOPENTADIENECARBOXALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>When included in a medicine for use on the lips the concentration of 6-methoxydicyclopentadiene carboxaldehyde must be no more than 0.1%.</p> <p>When included in dermal creams for infant use the concentration of 6-methoxydicyclopentadienecarboxaldehyde must be no more than 0.5%.</p> <p>When for dermal use or use on the hair the concentration of 6-methoxydicyclopentadienecarboxaldehyde must be no more than 0.5%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
274	6-METHYL COUMARIN	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

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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
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
275	6-METHYL-2-BUTEN-3-OL-2	E	
276	7-ACETYL-1,1,3,4,4,6-HEXAMETHYL TETRAHYDRONAPHTHALENE	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%.
277	7-METHYL-2H-1,5-BENZODIOXEPIN-3(4H)-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
278	7-OCTENE-1,6-DIOL, 3,7-DIMETHYL-	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
			fragrance concentration in a medicine must be no more than 1%.
279	7-PROPYL-2H-1,5-BENZODIOXEPIN-3(4H)-ONE	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%.
280	8,13:13,20-DIEPOXY-14,15-BISNORLABDANE	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%.
281	8-METHYL-1-OXASPIRO(4,5)DECAN-2-ONE	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
282	8-OCIMENYL 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%.
283	9-DECEN-1-OL	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%.
284	ABELMOSCHUS MOSCHATUS	A, H	
285	ABELMOSCHUS MOSCHATUS SUBSP. MOSCHATUS	A, H	
286	ABIES BALSAMEA	A, H	
287	ABIES NIGRA	A, H	
288	ABIES PECTINATA	A, H	
289	ABIES SIBIRICA	A, H	
290	ABRUS CANTONIENSIS	A, H	If the herbal substance is derived from the seed, the maximum recommended daily dose of Abrus cantoniensis must be no more than 1mg 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
			the dry seed.
291	ABUTILON THEOPHRASTI	A, H	
292	ACACIA	A, E, H	
293	ACACIA BAILEYANA	A, H	
294	ACACIA CATECHU	A, H	
295	ACACIA DEALBATA	A, H	
296	ACACIA DECURRENS	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%.
297	ACACIA FARNESIANA	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%.
298	ACACIA LONGIFOLIA	A, E, H	
299	ACACIA NILOTICA	A, E, H	

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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
300	ACACIA SENEGAL	A, E, H	
301	ACALYPHA INDICA	A, H	
302	ACANTHUS MOLLIS	A, H	
303	ACER CAMPESTRE	A, H	
304	ACER NEGUNDO	A, H	
305	ACER SACCHARINUM	A, H	
306	ACER SACCHARUM	A, E, H	
307	ACEROLA	E	
308	ACESULFAME POTASSIUM	E	
309	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%.
310	ACETALDEHYDE	E	Permitted for use only in combination with other permitted 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%.
311	ACETALDEHYDE ETHYL LINALYL ACETAL	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%.
312	ACETALDEHYDE ETHYL PHENYLETHYL ACETAL	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%.
313	ACETALDEHYDE PHENYLETHYL PROPYL ACETAL	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
314	ACETANISOLE	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%.
315	ACETIC ACID	E, H	The concentration in the medicine must be no more than 80%.
316	ACETOIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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
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Table 1 **Part 2**

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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
317	ACETOMENAPHTHONE	A, E	
318	ACETONE	E	The residual solvent limit for Acetone is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
319	ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
320	ACETOVANILLONE	E	Only for use in topical medicines for dermal application. Permitted for use only in combination with other permitted ingredients as a fragrance. If used as 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
321	ACETYL	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%.
322	ACETYL DIPEPTIDE-1 CETYL ESTER	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 0.01%.
323	ACETYL GLUCOSAMINE	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 0.5%. If the ingredient is sourced from seafood, then the medicine requires the following warning statement on the medicine label:

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
			- (SFOOD) 'Derived from seafood'
324	ACETYL HEXAMETHYL TETRALIN	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%.
325	ACETYL LEVOCARNITINE HYDROCHLORIDE	A, E	
326	ACETYL TRIFLUOROMETHYLPHENYL VALYLGLYCINE	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 0.5%.
327	ACETYLATED LANOLIN	E	Only for use in topical medicines for dermal application.
328	ACETYLATED LANOLIN ALCOHOL	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
329	ACETYLATED MONOGLYCERIDES	E	
330	ACETYLATED VETIVER 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%.
331	ACETYLCYSTEINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.001%.
332	ACHILLEA ERBA-ROTTA SUBSP. MOSCHATA	A, H	
333	ACHILLEA MILLEFOLIUM	A, E, H	Arbutin is a mandatory component of Achillea millefolium. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the

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 0.74 %.
334	ACHILLEA PTARMICA	A, H	
335	ACHYRANTHES ASPERA	A, H	
336	ACHYRANTHES BIDENTATA	A, H	
337	ACHYRANTHES FAURIEI	A, H	
338	ACID GREEN 25	E	Permitted for use only as a colour for topical use.
339	ACID RED 33	E	Permitted for use only as a colour for topical use.
340	ACID RED 87	E, H	Only for use as an active homoeopathic ingredient or for excipient use as a colour in topical medicines.
341	ACID TREATED WAXY MAIZE STARCH	E	
342	ACID-ISOMERISED LINALOOL	E	Permitted for use only when combined 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%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

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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
343	ACONITUM CARMICHAELII	A, H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum carmichaelii. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
344	ACONITUM FEROX	A, H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum ferox. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
345	ACONITUM KUSNEZOFFI	A, H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum kusnezoffii. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
346	ACONITUM NAPELLUS	A, H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum

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
			napellus. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
347	ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER	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 1.7%.
348	ACRYLAMIDES COPOLYMER	E	Only for use in topical medicines for dermal application.
349	ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
350	ACRYLATES/ACRYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application.
351	ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	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
352	ACRYLATES/C12-22 ALKYL METHACRYLATE COPOLYMER	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%.
353	ACRYLATES/DIMETHICONE COPOLYMER	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%.
354	ACRYLATES/OCTYLACRYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application.
355	ACRYLATES/STEARETH-20 METHACRYLATE COPOLYMER	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%.

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
356	ACRYLATES/VA COPOLYMER	E	Only for use in topical medicines for dermal application.
357	ACRYLIC ACID/VP CROSSPOLYMER	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 2.5%.
358	ACTAEA CIMICIFUGA	A, H	
359	ACTAEA HERACLEIFOLIA	A, H	
360	ACTAEA PACHYPODA	A, H	
361	ACTAEA RACEMOSA	A, H	When used in oral medicines, the medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your

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Table 1 **Part 2**

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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
			doctor.'
362	ACTAEA SIMPLEX	A, H	
363	ACTAEA SPICATA	A, H	
364	ACTINIDIA CHINENSIS	A, H	
365	ACTINIDIA DELICIOSA	A, H	
366	ACTIVATED ATTAPULGITE	A	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.
367	ACTIVATED CHARCOAL	A, E, H	When for internal use, the medicine requires the following warning statement on the medicine label: - (ACCOAL) 'Products containing activated charcoal should be used with caution in children since it may interfere with absorption of nutrients. Activated charcoal may interact with other medicines. Activated charcoal is not recommended for long-term use' (or words to that effect).

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
368	ADEMETIONINE DISULFATE DITOSYLATE DIHYDRATE	A, H	<p>(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate ditosylate dihydrate.</p> <p>Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
369	ADEMETIONINE DISULFATE TOSYLATE	A, H	<p>(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tosylate.</p> <p>Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under</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
			the supervision of a healthcare practitioner (or words to that effect)'
370	ADEMETIONINE DISULFATE TRITOSYLATE DIHYDRATE	A, H	<p>(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tritosylate dihydrate.</p> <p>Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
371	ADEMETIONINE HEXASULFATE DIHYDRATE	A, H	<p>(S)-S-Adenosylmethionine is a mandatory component of Ademetionine hexasulfate dihydrate.</p> <p>Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who 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
			using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
372	ADEMETIONINE HEXATOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine hexatosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
373	ADEMETIONINE PENTASULFATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine pentasulfate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning

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>statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
374	ADEMETIONINE PENTATOSYLATE DIHYDRATE	A, H	<p>(S)-S-Adenosylmethionine is a mandatory component of Ademetionine pentatosylate dihydrate.</p> <p>Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
375	ADEMETIONINE TETRASULFATE DIHYDRATE	A, H	<p>(S)-S-Adenosylmethionine is a mandatory component of Ademetionine tetrasulfate dihydrate.</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>Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'</p>
376	ADEMETIONINE TETRATOSYLATE DIHYDRATE	A, H	<p>(S)-S-Adenosylmethionine is a mandatory component of Ademetionine tetratosylate dihydrate.</p> <p>Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:</p> <p>- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (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
377	ADEMETHIONINE TRISULFATE DITOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine trisulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
378	ADENOPHORA STRICTA	A, H	
379	ADENOPHORA TRIPHYLLA	A, H	
380	ADENOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.04%.
381	ADENOSINE PHOSPHATE	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 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%.
382	ADENOSINE TRIPHOSPHATE	E	Only for use in topical medicines for dermal application.
383	ADENOSINE TRIPHOSPHATE DISODIUM	E	Only for use in topical medicines for dermal application.
384	ADIANTUM CAPILLUS-VENERIS	A, H	
385	ADIPIC ACID	E	
386	ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER	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%.
387	ADONIS VERNALIS	A, H	The concentration of equivalent dry Adonis vernalis in the medicine must be no more than 10mg/Kg or 10mg/L

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
			or 0.001%.
388	ADRENALINE (EPINEPHRINE)	H	Only for use as an active homoeopathic ingredient.
389	ADZUKI BEAN	E	
390	AEGOPODIUM PODAGRARIA	A, H	
391	AESCLUSUS CHINENSIS	A, H	
392	AESCLUSUS GLABRA	A, H	
393	AESCLUSUS HIPPOCASTANUM	A, H	
394	AESCLUSUS X CARNEA	A, H	
395	AETHUSA CYNAPIUM	H	Only for use as an active homoeopathic ingredient.
396	AGAR	A, E	
397	AGASTACHE RUGOSA	A, H	
398	AGATHOSMA BETULINA	A, E, H	Pulegone is a mandatory component of Agathosma betulina. The concentration of pulegone in the medicine must be no more than 4%.
399	AGAVE AMERICANA	A, E, H	
400	AGRIMONIA EUPATORIA	A, E, H	

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Table 1 **Part 2**

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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
401	AGRIMONIA REPENS	A, H	
402	AGROSTIS TENUIS	A, H	
403	AILANTHUS ALTISSIMA	A, H	
404	AJUGA CHAMAEPITYS	A, H	
405	AJUGA REPTANS	A, H	
406	ALANINE	A, E	
407	ALANYLGLUTAMINE	A	Only for use in oral medicines.
408	ALARIA ESCULENTA	A, H	Iodine is a mandatory component of Alaria esculenta. 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.
409	ALBIZIA JULIBRISSIN	A, H	
410	ALBIZIA LEBBECK	A, H	
411	ALCEA ROSEA	A, H	
412	ALCHEMILLA ALPINA	A, H	
413	ALCHEMILLA ARVENSIS	A, H	

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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
414	ALCHEMILLA VULGARIS	A, H	
415	ALETRIS FARINOSA	A, H	
416	ALETRIS SPICATA	A, H	
417	ALEURITES MOLUCCANUS SEED OIL	E	Only for use in topical medicines for dermal application.
418	ALFADEX	A, E	Only for use in oral medicines. The maximum daily dose must provide no more than 6 g of alfadex.
419	ALGINATE-KONJAC-XANTHAN POLYSACCHARIDE COMPLEX	A	Only for use in oral medicines. Only for use when the dosage form is other than tablet. The maximum recommended daily dose must be no more than 13.5 g. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'

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
			stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
420	ALGINIC ACID	E	
421	ALISMA ORIENTALE	A, H	
422	ALISMA PLANTAGO AQUATICA	A, H	
423	ALKANNA TINCTORIA	A, H	
424	ALKYL (C12-15) BENZOATE	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 21%.
425	ALLANTOIN	E	Only for use in topical medicines for dermal application.
426	ALLIARIA PETIOLATA	A, H	
427	ALLIUM CEPA	A, H	
428	ALLIUM FISTULOSUM	A, H	
429	ALLIUM HIEROCHUNTINUM	A, H	

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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
430	ALLIUM MACROSTEMON	A, H	
431	ALLIUM ODORUM	A, H	
432	ALLIUM PORRUM	A, H	
433	ALLIUM SATIVUM	A, E, H	
434	ALLIUM SCHOENOPRASUM	A, H	
435	ALLIUM URSINUM	A, H	
436	ALLO-OCIMENE	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%.
437	ALLURA RED AC	E	Permitted for use only as a colour for oral and topical use.
438	ALLURA RED AC ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
439	ALLYL ALPHA-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

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%.
440	ALLYL AMYL GLYCOLATE	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%.
441	ALLYL CAPRYLATE	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%.
442	ALLYL CYCLOHEXANEPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

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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
			fragrance concentration in a medicine must be no more 1%.
443	ALLYL CYCLOHEXYLOXYACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
444	ALLYL HEPTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
445	ALLYL HEPTYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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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
			flavour concentration in a medicine must be no more than 5%.
446	ALLYL HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
447	ALLYL ISOTHIOCYANATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. 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%.
448	ALLYL PHENOXYACETATE	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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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%.
449	ALLYL TIGLATE	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%.
450	ALMOND	E	
451	ALMOND OIL	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Almond oil. The concentration of Amygdalin in the medicine must be 0%. The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
452	ALNUS GLUTINOSA	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
453	ALNUS INCANA SUBSP. RUGOSA	A, H	
454	ALOE FERROX	A, E, H	<p>When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe ferox.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</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</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>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) or the chemical component(s)]; and - (LAX4) 'This product may have laxative effect'. <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> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.

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
455	ALOE PERRYI	A, H	<p>When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe perryi.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</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

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>water' [or words to that effect].</p> <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) or the chemical component(s)]; and - (LAX4) 'This product may have laxative effect'. <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> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
456	ALOE VERA	A, E, H	When the route of administration is oral or sublingual, Hydroxyanthracene

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 calculated as anhydrous barbaloin is a mandatory component of Aloe vera.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</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</p>

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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>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) or the chemical component(s)']; and - (LAX4) 'This product may have laxative effect'. <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> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
457	ALOES CAPE	A, H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloes

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>cape.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</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</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>on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and - (LAX4) 'This product may have laxative effect'. <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> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
458	ALOYSIA CITRODORA	A, H	
459	ALPHA CASOZEPINE ENRICHED HYDROLYSED MILK PROTEIN	A	<p>Only for use in oral medicines.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (BABY3) 'Not suitable for use in children under the age of

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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
			twelve months - except on professional advice' - (COWMK) 'Derived from cow's milk.'
460	ALPHA LIPOIC ACID	A	
461	ALPHA-2,2,6-TETRAMETHYL-CYCLOHEXENEBUTANAL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
462	ALPHA-AMYL CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
463	ALPHA-AMYL CINNAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a

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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
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
464	ALPHA-CEDRENE EPOXIDE	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%.
465	ALPHA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
466	ALPHA-FARNESENE	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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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%.
467	ALPHA-FURFURYL OCTANOATE	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%.
468	ALPHA-HEXYLCINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
469	ALPHA-IONOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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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>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>
470	ALPHA-IONONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
471	ALPHA-IRONE	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>

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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
472	ALPHA-ISO-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%.
473	ALPHA-METHYL ANISALACETONE	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%.
474	ALPHA-METHYL BENZYL 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%.

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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
475	ALPHA-METHYL BUTYRALDEHYDE	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%.
476	ALPHA-METHYL BUTYRIC 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%.
477	ALPHA-METHYL CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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
478	ALPHA-METHYL FURFURAL	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%.
479	ALPHA-METHYL NAPHTHYL 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%.
480	ALPHA-METHYLCINNAMYL 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%.
481	ALPHA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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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>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>
482	ALPHA-PHELLANDRENE	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>
483	ALPHA-PINENE	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
484	ALPHA-SINENSAL	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%.
485	ALPHA-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%.
486	ALPHA-TERPINEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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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
			medicine must be no more 1%.
487	ALPINIA GALANGA	A, H	
488	ALPINIA HAINANENSIS	A, H	
489	ALPINIA OFFICINARUM	A, H	
490	ALPINIA OXYPHYLLA	A, H	
491	ALSIDIUM HELMINTHOCHORTON	A, H	Iodine is a mandatory component of Alsidium helminthochorton. 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.
492	ALSTONIA BOONEI	A, H	
493	ALSTONIA CONSTRICTA	H	Only for use as an active homoeopathic ingredient.
494	ALTERNANTHERA PHILOXEROIDES	A, H	
495	ALTEROMONAS FERMENT EXTRACT	E	Only for use in topical medicines for dermal application and not to be

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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
			included in medicines intended for use on damaged skin or in the eye. The concentration in the medicine must be no more than 0.3%.
496	ALTHAEA OFFICINALIS	A, E, H	
497	ALUM DODECAHYDRATE	A, E, H	
498	ALUMINIUM CHLOROHYDRATE	E	Only for use in topical medicines for dermal application.
499	ALUMINIUM CITRATE	E	Only for use in topical medicines for dermal application.
500	ALUMINIUM DISTEARATE	E	Only for use in topical medicines for dermal application.
501	ALUMINIUM HYDROXIDE	E	Only for use in topical medicines for dermal application.
502	ALUMINIUM HYDROXIDE HYDRATE	E	Only for use in topical medicines for dermal application.

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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
503	ALUMINIUM MAGNESIUM SILICATE	E	
504	ALUMINIUM MONOSTEARATE	E	Only for use in topical medicines for dermal application.
505	ALUMINIUM OXIDE	E, H	When used as an excipient ingredient, only for use in topical medicines for dermal application. When used as an active ingredient, only for use in homoeopathic medicines.
506	ALUMINIUM SILICATE	E, H	Only for use as an active homoeopathic or excipient ingredient. When used as an excipient ingredient, the medicine is only for use in topical medicines for dermal application.
507	ALUMINIUM SODIUM SILICATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:

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
			- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
508	ALUMINIUM STARCH OCTENYLSUCCINATE	E	The concentration in the medicine must be no more than 7%.
509	ALUMINIUM STEARATE	E	Only for use in topical medicines for dermal application.
510	ALUMINIUM SULFATE HYDRATE	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%.
511	AMARANTH	E	Permitted for use only as a colour for oral and topical use.
512	AMARANTH ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use

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
513	AMARANTHUS HYBRIDUS	A, H	
514	AMARANTHUS RETROFLEXUS	A, H	
515	AMBERGRIS EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a fragrance. The total fragrance concentration in a medicine must be no more than 1%.
516	AMBRETTE SEED 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%.
517	AMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 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
518	AMBRINOL	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%.
519	AMBROSIA ARTEMISIIFOLIA	A, H	
520	AMBROSIA PSILOSTACHYA	A, H	
521	AMINOBENZOIC ACID	A	Only for use as an active ingredient in sunscreens. 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 15%.
522	AMINOCAPROIC ACID	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%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
523	AMINOPROPYL ASCORBYL PHOSPHATE	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%.
524	AMMI VISNAGA	A, H	The concentration of equivalent dry Ammi visnaga in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
525	AMMONIA	E, H	Only for use as an active homoeopathic or excipient ingredient. When used as an excipient ingredient, the medicine is only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
526	AMMONIO METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
527	AMMONIUM ACRYLATES COPOLYMER	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
528	AMMONIUM ACRYLATES/ACRYLONITROGENS COPOLYMER	E	Only for use in topical medicines for dermal application.
529	AMMONIUM ACRYLOYLDIMETHYLTAURATE/ STEARETH-8 METHACRYLATE 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 0.5%.
530	AMMONIUM ACRYLOYLDIMETHYLTAURATE/ VP 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 5%.
531	AMMONIUM BICARBONATE	A, H	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

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
			time.
532	AMMONIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
533	AMMONIUM CARBONATE	E, H	Only for use as an active homoeopathic or excipient ingredient.
534	AMMONIUM CHLORIDE	A, E, H	Only for use as an active ingredient in homoeopathic medicines or as an uncompounded medicine substance packed for retail sale. When used as an uncompounded medicine substance the ingredient must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. If used as an excipient ingredient then the medicine is only for topical use for dermal application.
535	AMMONIUM GLYCYRRHIZINATE	E	
536	AMMONIUM IODIDE	H	Only for use an active ingredient in homoeopathic

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.
537	AMMONIUM LACTATE	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%.
538	AMMONIUM LAURETH SULFATE	E	Only for use in topical medicines for dermal application.
539	AMMONIUM LAURYL SULFATE	E	Only for use in topical medicines for dermal application.
540	AMMONIUM 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 0.2%.
541	AMMONIUM POLYACRYLOYLDIMETHYL	E	Only for use in topical medicines for dermal application and not to be

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Table 1 **Part 2**

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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
	TAURATE		included in medicines intended for use in the eye. The concentration must be no more than 3%.
542	AMMONIUM SULFIDE	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%.
543	AMOMUM AROMATICUM	A, H	
544	AMOMUM VILLOSUM	A, H	
545	AMORPHOPHALLUS KONJAC	A, H	Only for use when the dosage form is not tablet.
546	AMPELODESMOS MAURITANICUS	A, H	
547	AMPELOPSIS JAPONICA	A, H	
548	AMYL ACETATE	E	Only for use in topical medicines for dermal application.
549	AMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

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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
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
550	AMYL BENZOATE	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%.
551	AMYL 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%.
552	AMYL CAPROATE	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 flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
553	AMYL 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%.
554	AMYL CINNAMIC 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%.
555	AMYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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
			<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>
556	AMYL ISOBUTYRATE	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>
557	AMYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
558	AMYL OCTANOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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Table 1 **Part 2**

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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
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
559	AMYL PHENYLACETATE	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%.
560	AMYL 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%.
561	AMYL 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%.

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
562	AMYL VALERATE	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%.
563	AMYL VINYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
564	AMYL VINYL CARBINYL 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

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%.
565	AMYLASE	A	<p>Amylase must be derived from <i>Aspergillus oryzae</i>, and comply with the relevant compositional guideline.</p> <p>When used in a divided preparation, the allowed unit is Alpha-amylase dextrinising unit or Thousand alpha-amylase dextrinising unit.</p> <p>When used as an undivided preparation, the allowed unit is Thousand alpha-amylase dextrinising unit per gram or Dextrinising unit per gram.</p>
566	AMYLCYCLOHEXYL ACETATE (MIXED ISOMERS)	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>
567	AMYLOPECTIN	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</p>

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

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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
			medicine must be no more than 5%.
568	AMYRIS BALSAMIFERA	A, H	
569	AMYRIS OIL WEST INDIAN	A, E, H	
570	ANACARDIUM OCCIDENTALE	A, H	
571	ANACYCLUS PYRETHRUM	A, H	
572	ANACYSTIS NIDULANS FERMENT	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 0.0025%.
573	ANAESTHETIC ETHER	H	Only for use as an active homoeopathic ingredient.
574	ANAGALLIS ARVENSIS	A, H	
575	ANAMIRTA COCCULUS	A, H	Picrotoxin is a mandatory component of Anamirta cocculus. The concentration of picrotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.

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Table 1 **Part 2**

Volume 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
576	ANANAS COMOSUS	A, E, H	
577	ANAPHALIS SINICA	A, H	
578	ANDROGRAPHIS PANICULATA	A, H	
579	ANEMARRHENA ASPHODELOIDES	A, E, H	
580	ANEMONE ALTAICA	A, H	
581	ANEMONE CHINENSIS	A, H	
582	ANEMONE HEPATICA	A, H	
583	ANEMONE PULSATILLA	A, H	
584	ANEMONE RADDEANA	A, H	
585	ANETHOLE	E	
586	ANETHOLEA ANISATA	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%.
587	ANETHUM GRAVEOLENS	A, E, H	
588	ANGELICA ACUTILOBA	A, H	
589	ANGELICA ANOMALA	A, H	
590	ANGELICA ARCHANGELICA	A, E, H	
591	ANGELICA ATROPURPUREA	A, H	

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

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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
592	ANGELICA DAHURICA	A, E, H	
593	ANGELICA DECURSIVA	A, H	
594	ANGELICA POLYMORPHA	A, E, H	
595	ANGELICA PUBESCENS	A, E, H	
596	ANGELICA ROOT DRY	A, H	
597	ANGELICA ROOT OIL	A, E, H	
598	ANGELICA SEED OIL	A, E, H	
599	ANGELICA STEM	E	
600	ANIBA ROSAEODORA	A, E, H	
601	ANISALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
602	ANISE ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

Volume 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
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
603	ANISE OIL	A, E, H	When the concentration of Anise oil in the preparation is more than 50% the nominal capacity of the container must be no more than 50 mL. When the concentration of Anise oil in the preparation is more than 50% and the nominal capacity of the container is 50 mL or less, a restricted flow insert must be fitted on the container. The medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children (or word to that effect)'
604	ANISEED	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine
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Table 1 **Part 2**

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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
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
605	ANISEED DRY	A, E, H	
606	ANISEED POWDER	A, E, H	
607	ANISIC ACID	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
608	ANISYL 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%.
609	ANISYL 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%.
610	ANISYL 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%.
611	ANISYL PROPIONATE	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%.
612	ANNATTO	E	Permitted for use only 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
			colour for oral and topical use.
613	ANOGEISSUS LATIFOLIA	A, E, H	
614	ANTENNARIA DIOICA	A, E, H	
615	ANTHOCYANINS	E	
616	ANTHOXANTHUM ODORATUM	A, H	When used as an active ingredient, coumarin is a mandatory component of Anthoxanthum odoratum and the concentration of coumarin in the medicine must be no more than 0.001%.
617	ANTHRISCUS CEREFOLIUM	A, H	
618	ANTHYLLIS VULNERARIA	A, H	
619	ANTIMONY POTASSIUM TARTRATE TRIHYDRATE	H	Only for use as an active homoeopathic ingredient.
620	ANTIMONY TRISULFIDE	H	Only for use as an active homoeopathic ingredient.
621	APIUM GRAVEOLENS	A, E, H	
622	APOCYNUM CANNABINUM	A, H	The concentration of equivalent dry Apocynum cannabinum in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.

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Table 1 **Part 2**

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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
623	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	H	Only for use as an active homoeopathic ingredient.
624	APPLE	E	
625	APPLE CIDER VINEGAR	E	
626	APPLE ESSENCE NATURAL	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%.
627	APPLE 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%.
628	APPLE FIBRE	E	
629	APRICOT	E	
630	APRICOT KERNEL OIL PEG-6 ESTERS	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
631	AQUILARIA MALACCENSIS	A, H	
632	AQUILARIA SINENSIS	A, H	
633	AQUILEGIA VULGARIS	A, H	
634	ARACHIDONIC ACID	E	Only for use in topical medicines for dermal application.
635	ARACHIDYL ALCOHOL	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%.
636	ARACHIDYL 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 must be no more than 0.5%.
637	ARACHIDYL PROPIONATE	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
638	ARACHIS HYPOGAEA	A, E, H	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
639	ARACHIS OIL	A, E, H	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
640	ARALIA CORDATA	A, H	
641	ARALIA HISPIDA	A, H	
642	ARALIA NUDICAULIS	A, H	
643	ARALIA RACEMOSA	A, H	
644	ARCTIUM LAPPA	A, E, H	
645	ARCTIUM MINUS	A, H	
646	ARCTOSTAPHYLOS UVA-URSI	A, E, H	Arbutin is a mandatory component of <i>Arctostaphylos uva-ursi</i> . The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than

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Table 1 **Part 2**

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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
			0.74 %.
647	ARDISIA JAPONICA	A, H	
648	ARECA CATECHU	A, H	Arecoline is a mandatory component of Areca catechu. The concentration of arecoline in the medicine must be no more than 10 mg/Kg or 10 mg/L or 0.001%.
649	ARGANIA SPINOSA KERNEL OIL	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 5% in the medicine.
650	ARGININE	A, E, H	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (ARGIN1) 'This medicine contains arginine and is intended to be applied to the skin only and not to the mucosa - vagina or rectum.'

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Table 1 **Part 2**

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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
651	ARGININE FERULATE	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 0.05%.
652	ARISAEMA ATRORUBENS	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
653	ARISAEMA CONSANGUINEUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
654	ARISAEMA JAPONICUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
655	ARMORACIA RUSTICANA	A, E, H	Volatile oil components (of <i>Armoracia rusticana</i>) is a mandatory component of <i>Armoracia rusticana</i> . The maximum recommended daily dose must contain no

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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 20 mg of volatile oil components (of <i>Armoracia rusticana</i>).
656	ARNEBIA EUCHROMA	A, H	
657	ARNICA FLOWER DRY	A, H	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than 1mg of the equivalent dry flower of <i>Arnica montana</i> .
658	ARNICA MOLLIS	A, H	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
659	ARNICA MONTANA	A, H	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of <i>arnica montana</i> .
660	ARRHENATHERUM ELATIUS	A, H	
661	ARROWROOT	A, E, H	
662	ARSENIC TRIIODIDE	H	Only for use as an active homoeopathic ingredient. The

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Table 1 **Part 2**

Volume 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
			concentration of arsenic in the medicine must be no more than 0.001%.
663	ARSENIC TRIOXIDE	H	Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than 0.001%.
664	ARTEMISIA ABROTANUM	A, H	Thujone is a mandatory component of Artemisia abrotanum. The concentration of thujone from Artemisia abrotanum in the medicine must be no more than 4%.
665	ARTEMISIA ABSINTHIUM	A, H	Thujone is a mandatory component of Artemisia absinthium. The concentration of thujone from Artemisia absinthium in the medicine must be no more than 4%.
666	ARTEMISIA ANNUA	A, H	Thujone is a mandatory component of Artemisia annua. The concentration of thujone from Artemisia annua 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%.
667	ARTEMISIA ARBORESCENS	A, H	Thujone is a mandatory component of Artemisia arborescens. The concentration of thujone from Artemisia arborescens in the medicine must be no more than 4%.
668	ARTEMISIA ARGYI	A, H	Thujone is a mandatory component of Artemisia argyi. The concentration of thujone from Artemisia argyi in the medicine must be no more than 4%.
669	ARTEMISIA DRACUNCULUS	A, E, H	Thujone is a mandatory component of Artemisia dracunculus. The concentration of thujone from Artemisia dracunculus in the medicine must be no more than 4%.
670	ARTEMISIA FRIGIDA	A, H	Thujone is a mandatory component of Artemisia frigida. The concentration of thujone from Artemisia frigida 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%.
671	ARTEMISIA HERBA-ALBA	A, H	<p>Thujone is a mandatory component of Artemisia herba-alba.</p> <p>The concentration of thujone from Artemisia herba-alba in the medicine must be no more than 4%.</p>
672	ARTEMISIA MARITIMA	A, H	<p>Thujone is a mandatory component of Artemisia maritima.</p> <p>The concentration of thujone from Artemisia maritima in the medicine must be no more than 4%.</p>
673	ARTEMISIA 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>

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
674	ARTEMISIA PALLENS	A, E, H	Thujone is a mandatory component of Artemisia pallens. The concentration of thujone from Artemisia pallens in the medicine must be no more than 4%.
675	ARTEMISIA TRIDENTATA	A, H	Thujone is a mandatory component of Artemisia tridentata. The concentration of thujone from Artemisia tridentata in the medicine must be no more than 4%.
676	ARTEMISIA VULGARIS	A, E, H	Thujone is a mandatory component of Artemisia vulgaris. The concentration of thujone from Artemisia vulgaris in the medicine must be no more than 4%.
677	ARTERY	H	Only for use as an active homoeopathic ingredient.
678	ARTHROSPIRA MAXIMA	A, H	

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Table 1 **Part 2**

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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
679	ARTHROSPIRA PLATENSIS	A, H	
680	ARUM MACULATUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
681	ASAFOETIDA GUM	A, H	
682	ASAFOETIDA 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%.
683	ASARUM EUROPAEUM	A, H	
684	ASARUM HETEROTROPOIDES	A, H	
685	ASARUM OIL	E	
686	ASARUM SIEBOLDII	A, E, H	
687	ASCLEPIAS TUBEROSA	A, H	
688	ASCOPHYLLUM NODOSUM	A, E, H	Iodine is a mandatory component of Ascophyllum nodosum. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.

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
			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
689	ASCORBIC ACID	A, E	
690	ASCORBYL 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 2%.
691	ASCORBYL METHYLSILANOL PECTINATE	E	Only for use in topical medicines for dermal application.
692	ASCORBYL PALMITATE	A, E	When for oral use, the maximum recommended daily dose must contain no more than 100mg of ascorbyl palmitate.
693	ASCORBYL TOCOPHERYL MALEATE	E	Only for use as an ingredient in topical medicines for dermal application and not to be

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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
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0575%.
694	ASPALATHUS LINEARIS	A, E, H	
695	ASPARAGINE	A, E	
696	ASPARAGOPSIS SULFATED GALACTANS	E	Only for use as an ingredient 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 0.0025%.
697	ASPARAGUS	E, H	Only for use as an active homoeopathic or excipient ingredient.
698	ASPARAGUS COCHINCHINENSIS	A, H	
699	ASPARAGUS OFFICINALIS	A, E, H	
700	ASPARAGUS RACEMOSUS	A, H	The plant part must be dried, peeled root, and water extracts or ethanol/water extracts (containing up to 45% ethanol) of the dried, peeled root.

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
701	ASPARTAME	E	When for oral use, the medicine requires the following warning statement on the medicine label: - (PKU) 'Phenylketonurics are warned that this product contains phenylalanine (or words to that effect)' The medicine requires the following warning statement on the medicine label: - (ASPAR) 'Contains aspartame'
702	ASPARTIC ACID	A, E	
703	ASPERGILLUS ORYZAE	A, E, H	
704	ASTAXANTHIN ESTERS EXTRACTED FROM HAEMATOCOCCUS PLUVIALIS	A	Only for use in oral medicines. Astaxanthin (of Haematococcus pluvialis) is a mandatory component of astaxanthin esters extracted from Haematococcus pluvialis. The maximum daily dose must contain no more than 12mg of Astaxanthin (of Haematococcus pluvialis).
705	ASTER NOVI-BELGII	A, H	

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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
706	ASTER TATARICUS	A, H	
707	ASTRAGALUS ADSURGENS	A, H	
708	ASTRAGALUS COMPLANATUS	A, H	
709	ASTRAGALUS EXCARPUS	A, H	
710	ASTRAGALUS GUMMIFER	A, E, H	
711	ASTRAGALUS LENTIGINOSUS	A, H	
712	ASTRAGALUS MEMBRANACEUS	A, E, H	
713	ASTRAGALUS PENDULIFLORUS	A, H	
714	ASTROCARYUM MURUMURU SEED TRIGLYCERIDES	E	Only for use as an ingredient 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 0.21%.
715	ATRACTYLODES JAPONICA	A, H	
716	ATRACTYLODES LANCEA	A, H	
717	ATRACTYLODES MACROCEPHALA	A, H	
718	ATROPA BELLADONNA	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Atropa belladonna. The concentration of alkaloids calculated as hyoscyamine in

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
			the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
719	ATROPINE SULFATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
720	ATTALEA SPECIOSA	E	Only for use in topical medicines for dermal application.
721	AURA B-AURANTIOL	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%.
722	AUREOBASIDIUM PULLULANS	A, H	
723	AVENA FATUA	A, H	Gluten is a mandatory component of Avena fatua when the plant part is seed and the route of administration is

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>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>
724	AVENA SATIVA	A, E, H	<p>Gluten is a mandatory component of Avena sativa when the plant part is seed and 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>
725	AVOCADO	E	
726	AVOCADO OIL	E	
727	AVOCADO OIL UNSAPONIFIABLES	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
728	AZADIRACHTA INDICA	A, H	<p>The ingredient can only be derived from the plant part seed and must be cold pressed or debitterised oil.</p> <p>“Debitterised neem seed oil” means highly purified oil from the neem seed containing only fatty acids and glycerides of fatty acids.</p> <p>Cold pressed Azadirachta indica seed oil must be for topical use for dermal application only.</p> <p>When the concentration of cold pressed Azadirachta indica seed oil is more than 1%, a child resistant closure must be fitted to the container.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect).' - (NTAKEN) 'Not to be taken (or words to that effect).' - (CHILD) 'Keep out of reach of children (or words to that effect).'

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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
729	AZOVAN BLUE	E	Permitted for use only as a colour for topical use.
730	AZULENE	E	Only for use in topical medicines for dermal application.