



Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2019

I, Cheryl McRae, as delegate of the Minister for Health, make the following determination.

Dated 14 November 2019

Cheryl McRae
Assistant Secretary
Complementary and Over the Counter Medicines Branch
Health Products Regulation Group
Department of Health

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Note: This instrument is in 6 volumes:

Volume 1:	Sections 1–7 (pages 1-3)
	Schedule 1 (1,7,7-TRIMETHYLBICYCLO(2.2.1)HEPT-2-YL)-CYCLOHEXANOL)–AZULENE (pages 4 -152)
Volume 2:	Schedule 1 BACILLUS COAGULANS –EVERNIA PRUNASTRA EXTRACT (pages 153-444)
Volume 3:	Schedule 1 FABIANA IMBRICATA–JUSTICIA ADHATODA (pages 445-592)
Volume 4:	Schedule 1 KADSURA COCCINEA–OYSTER SHELL (pages 593-755)
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Volume 6:	Schedule 1 UBIDECARENONE–ZUCCHINI (pages 1052-1089)
	Schedule 2 (page 1090)

1 Name

This instrument is the *Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2019*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 26BB(1) of the *Therapeutic Goods Act 1989*.

4 Interpretation

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) British Pharmacopoeia;
- (b) European Pharmacopoeia;
- (c) medicine;
- (d) Register; and
- (e) United States Pharmacopoeia-National Formulary.

- (1) In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active ingredient, or **A**, for a medicine, has the same meaning as in the Regulations.

code tables means the tables accessed via the *Code Tables* item in the *Public TGA Information* menu in TGA eBusiness Services.

excipient or **E**, for a medicine, 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.

homoeopathic preparation has the same meaning as in the Regulations.

homoeopathic preparation ingredient or **H**, means an ingredient that is a constituent of a homoeopathic preparation.

Regulations means the *Therapeutic Goods Regulations 1990*.

TGA eBusiness Services means TGA eBusiness Services on the Therapeutic Goods Administration website which may be accessed on the internet at www.ebs.tga.gov.au.

Therapeutic Goods Administration has the same meaning as in the Regulations.

- (2) To avoid doubt, the terms set out in closed brackets in column 4 of the table in Schedule 1 to this instrument, which are associated with warning statements in relation to particular ingredients, are:
- (a) terms from the code tables under the headings Indications or Product Warning; and
 - (b) not required to be reproduced in a warning statement on the label of a medicine.

Note: Examples of these terms include the following:

- (a) (ARGIN1);
- (b) (CHILD3);
- (c) (GLUTEN);
- (d) (PEANUT); and
- (e) (PREGNT).

5 Permissible ingredients

The ingredients specified in column 2 of the table in Schedule 1 to this instrument are specified for the purposes of paragraph 26BB(1)(a) of the Act.

6 Requirements in relation to permissible ingredients being contained in medicine

For an ingredient mentioned in column 2 of an item in the table in Schedule 1 to this instrument, the following requirements are specified for the purposes of paragraph 26BB(1)(b) of the Act:

- (a) the ingredient must only be used in a medicine for a purpose specified in relation to the ingredient in column 3 of that item;
- (b) the ingredient must comply with the requirements specified in relation to the ingredient in column 4 of that item;
- (c) if the ingredient is derived from animal origin—the safety of the ingredient must have been assessed against, and comply with, the principles and requirements 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*.

7 Repeals

Each instrument that is specified in Schedule 2 to this instrument is repealed as set out in the applicable items in that Schedule.

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

Volume 1

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

Note: See sections 5 and 6.

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
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%.
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.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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. If used in a flavour the total flavour concentration in 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%.
8	(S)-LACTIC ACID	A, E, H	
9	(S)-S-ADENOSYLMETHIONINE DISULFATE DITOSYLATE	A	(S)-S-Adenosylmethionine is a mandatory component of

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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	DIHYDRATE		(S)-S-Adenosylmethionine disulfate 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)'
10	(S)-S-ADENOSYLMETHIONINE DISULFATE TOSYLATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tosylate. (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)'
11	(S)-S-ADENOSYLMETHIONINE DISULFATE TRITOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tritosylate dihydrate. (S)-S-Adenosylmethionine in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<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>
12	(S)-S-ADENOSYLMETHIONINE HEXASULFATE DIHYDRATE	A	<p>(S)-S-Adenosylmethionine is a mandatory component of (S)-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</p>

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Permissible ingredients and requirements			
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			<p>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>
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</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>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>
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 label:</p> <p>- (SAME) 'Individuals who are using prescription anti-</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			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 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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in 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%.
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 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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
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 than 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 flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour or a fragrance. If used in a flavour the total flavour concentration in a 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-5,16-DIONE	E	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%.
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]DECA N-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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 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-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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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 than 1%.
40	1-HEXEN-3-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%.
41	1-METHOXY-4-PROPENYLBENZENE	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			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 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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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 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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			fragrance concentration in a medicine must be no more than 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 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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
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%.
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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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 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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in 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%.
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 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

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Item	Ingredient name	Purpose	Specific requirements
			mg of 2,4-Decadienal.
70	2,4-DIMETHYL BUTADIENEACROLEIN	E	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%.
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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
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 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 13.5 mg of 2,4-Hexadienol.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
77	2,5-DIETHYLTETRAHYDROFURAN	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%.
78	2,5-DIMETHYL-2-OCTEN-6-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%.
79	2,5-DIMETHYL-4-ETHOXY-3(2H)-FURANONE	E	Only for use in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
80	2,5-DIMETHYL-4-HYDROXY-3(2H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in the medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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

Volume 1

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 1%.
81	2,5-DIMETHYL-4-METHOXY-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%.
82	2,5-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance, or a printing ink. If used in a flavour the total flavour concentration in 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%. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
83	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

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

Volume 1

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			fragrance concentration in a medicine must be no more than 1%.
84	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%.
85	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 5%.
86	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%.
87	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
88	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%.
89	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%.
90	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 than 1%.
91	2,6-NONADIEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a

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Volume 1

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
92	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%.
93	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%.
94	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%.
95	2-(2-METHYLPHENYL)ETHANOL	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as part of a fragrance proprietary excipient formulation. The ingredient is not to be included in medicines intended for use in the eye. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
96	2-[(3,7-DIMETHYL-6-OCTEN-1-YLIDENE)AMINO]BENZOIC ACID, METHYL ESTER	E	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%.
97	2-[1-(3,3-DIMETHYLCYCLOHEXYL)ETHOXY]-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%.
98	2-[1-(3,3-DIMETHYLCYCLOHEXYL)ETHOXY]-2-OXOETHYL PROPANOATE	E	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%.
99	2-ACETYLFURAN	E	Permitted for use only in

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Volume 1

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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-ACETYLPIRAZINE	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%.
101	2-ACETYLPIRIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
102	2-AMINO-2-METHYL-1-PROPANOL	E	Only for use in topical medicines for dermal application.
103	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			fragrance concentration in a medicine must be no more than 1%.
104	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%.
105	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 1%.
106	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%.
107	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%.
108	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 medicine must be no more than 1%.
109	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 than 1%.
110	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%.
111	2-ETHOXYETHANOL	E	The residual solvent limit for 2-Ethoxyethanol is 1.6 mg per

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>maximum recommended daily dose.</p> <p>The concentration in the medicine must be no more than 0.016%.</p>
112	2-ETHYL-1-HEXANOL	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>
113	2-ETHYL-3,5-DIMETHYLPYRAZINE	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 than 1%.</p>
114	2-ETHYL-3,6-DIMETHYLPYRAZINE	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 than 1%.</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
115	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%.
116	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 than 1%.
117	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%.
118	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%.
119	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 than 1%.
120	2-ETHYL-N-METHYL-N-(3-METHYLPHENYL) BUTANAMIDE	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
121	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%.
122	2-HEPTANOL	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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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
123	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 than 1%.
124	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%.
125	2-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
126	2-HYDROXYACETOPHENONE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1%.
127	2-ISOBUTYL-3-METHOXYPIRAZINE	E	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-ISOBUTYL-4-METHYLTETRAHYDRO-2H-PYRAN-4-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%.
129	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%.
130	2-ISOPROPYL-4-METHYLTHIAZOLE	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
131	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 5%.
132	2-METHOXY-3-(1-METHYLPROPYL)PYRAZINE	E	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%.
133	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%.
134	2-METHYL BUTYRIC ACID	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
135	2-METHYL HEPTANOIC 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>
136	2-METHYL-2-PENTENOIC 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>
137	2-METHYL-2-VINYL-5-ISOPROPENYL TETRAHYDROFURAN	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>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
138	2-METHYL-3-(3,4-METHYLENEDIOXYPHENYL)PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
139	2-METHYL-3-(4-METHOXYPHENYL)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%.
140	2-METHYL-3-[4-(2-METHYLPROPYL)PHENYL]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%.
141	2-METHYL-3-BUTEN-2-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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
142	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%.
143	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%.
144	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.
145	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
146	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%.
147	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%.
148	2-METHYL-5-(METHYLTHIO)FURAN	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-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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
150	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%.
151	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%.
152	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%.
153	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%.
154	2-METHYLHEXANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
155	2-METHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
156	2-METHYLTETRAHYDROFURAN-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%.
157	2-METHYLUNDECANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			1%.
158	2-METHYLVALERIC 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%.
159	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 than 1%.
160	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%.
161	2-OXOBUTYRIC 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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 5%.
162	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%.
163	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%.
164	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%.
165	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
166	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 than 1%.
167	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 than 1%.
168	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 than 1%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
169	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%.
170	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%.
171	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%.
172	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%.
173	2-TRANS-6-CIS-NONADIENAL	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
174	2-TRIDECANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
175	2-TRIDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
176	2-TRIDECENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
177	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%.
178	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%.
179	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%.
180	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 fragrance concentration in a medicine must be no more

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 1%.
181	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%.
182	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%.
183	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%.
184	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%.
185	3,5-DIMETHOXYTOLUENE	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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%.
186	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%.
187	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 fragrance concentration in a medicine must be no more than 1%.
188	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%.
189	3,7-DIMETHYL-1-OCTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<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>
190	3,7-DIMETHYL-1-OCTEN-3-OL	E	<p>Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.</p>
191	3,7-DIMETHYL-2,6-NONADIENENITRILE	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>
192	3,7-DIMETHYL-7-METHOXYOCTAN-2-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 fragrance concentration in a medicine must be no more than 1%.</p>
193	3-(3-ISOPROPYLPHENYL)BUTANAL	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
194	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%.
195	3-(4-HYDROXYPHENYL)-1-(2,4,6-TRIHYDROXYPHENYL)-1-PROPANONE	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%.
196	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%.
197	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 1%.
198	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%.
199	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 than 1%.
200	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%.
201	3-ETHYLPYRIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
202	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%.
203	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%.
204	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%.
205	3-ISO-CAMPHYL-5-CYCLOHEXAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
206	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%.
207	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%.
208	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 1%.
209	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 1%.
210	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%.
211	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%.
212	3-METHYL-5-PHENYLPENTANOL	E	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%.
213	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
214	3-METHYLCYCLOPENTADECANON E	E	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%.
215	3-METHYLCYCLOPENTADECENON E	E	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%.
216	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%.
217	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 than 1%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
218	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%.
219	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%.
220	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 than 1%.
221	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
222	3-PHENYLPROPYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
223	3-PROPYLIDENE PHTHALIDE	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 than 1%.</p>
224	3-TRANS-ISOCAMPHYLCYCLOHEXANOL	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>
225	3A,6,6,9A-	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	TETRAMETHYLDODECAHYDRON APHTHO[2,1-B] FURAN		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%.
226	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%.
227	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%.
228	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 flavour concentration in a medicine must be no more than 5%.
229	4,7-METHANO-1H-INDENEMETHANOL, OCTAHYDRO-, ACETATE	E	Permitted for use only in combination with other permitted ingredients as part

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
230	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%.
231	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%.
232	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%.
233	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in 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%.
234	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%.
235	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%.
236	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 than 1%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
237	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 than 1%.
238	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%.
239	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 than 1%.
240	4-HEPTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
241	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%.
242	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%.
243	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%.
244	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 flavour concentration in a medicine must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
245	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%.
246	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%.
247	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%.
248	4-METHYL-5-THIAZOLETHANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			1%.
249	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 words to this effect). <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).

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
250	4-METHYLPENTANOIC 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-METHYLPHENYL OCTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
252	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%.
253	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
254	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%.
255	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%.
256	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%.
257	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%.
258	5,7-DIHYDRO-2-METHYLTHIENO (3,4D) PYRIMIDINE	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
259	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%.
260	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 than 1%.
261	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 medicine must be no more than 1%.
262	5-ETHYL-3-HYDOXY-4-METHYL-	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	2(5H)-FURANONE		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%.
263	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%.
264	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%.
265	5-METHOXYPSORALEN	E	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%.
266	5-METHYL 2-PHENYL HEXEN-2-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
267	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%.
268	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 1%.
269	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%.
270	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%.
271	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%.
272	6,6-DIMETHYL-2-NORPINENEPROPIONALDEHYDE	E	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%.
273	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%.
274	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
275	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 1%.
276	6-METHOXYDICYCLOPENTADIENE CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. When included in a medicine for use on the lips the concentration of 6-methoxydicyclopentadiene carboxaldehyde must be no more than 0.1%. When included in dermal creams for infant use the concentration of 6-methoxydicyclopentadienecarboxaldehyde must be no more than 0.5%. When for dermal use or use on the hair the concentration of 6-methoxydicyclopentadienecarboxaldehyde must be no more than 0.5%. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
277	6-METHYL COUMARIN	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
278	6-METHYL-2-BUTEN-3-OL-2	E	
279	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%.
280	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 than 1%.
281	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 fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
282	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%.
283	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%.
284	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%.
285	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%.
286	9-DECEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
287	ABELMOSCHUS MOSCHATUS	A, H	
288	ABELMOSCHUS MOSCHATUS SUBSP. MOSCHATUS	A, H	
289	ABIES BALSAMEA	A, H	
290	ABIES NIGRA	A, H	
291	ABIES PECTINATA	A, H	
292	ABIES SIBIRICA	A, H	
293	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 the dry seed.
294	ABUTILON THEOPHRASTI	A, H	
295	ACACIA	A, E, H	
296	ACACIA BAILEYANA	A, H	
297	ACACIA CATECHU	A, H	
298	ACACIA DEALBATA	A, H	
299	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%.
300	ACACIA FARNESIANA	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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%.
301	ACACIA LONGIFOLIA	A, E, H	
302	ACACIA NILOTICA	A, E, H	
303	ACACIA SENEGAL	A, E, H	
304	ACALYPHA INDICA	A, H	
305	ACANTHUS MOLLIS	A, H	
306	ACER CAMPESTRE	A, H	
307	ACER NEGUNDO	A, H	
308	ACER SACCHARINUM	A, H	
309	ACER SACCHARUM	A, E, H	
310	ACEROLA	E	
311	ACESULFAME POTASSIUM	E	
312	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 than 1%.
313	ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
314	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%.
315	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%.
316	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%.
317	ACETANISOLE	E	Permitted for use only: (a) in topical medicines for

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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%.
318	ACETIC ACID	E, H	The concentration in the medicine must be no more than 80%.
319	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 than 1%.
320	ACETOMENAPHTHONE	A, E	
321	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%.
322	ACETOPHENONE	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
323	ACETOVANILLONE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
324	ACETYL	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>
325	ACETYL DIPEPTIDE-1 CETYL ESTER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 0.01%.
326	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: - (SFOOD) 'Derived from seafood'
327	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%.
328	ACETYL LEVOCARNITINE HYDROCHLORIDE	A, E	
329	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%.
330	ACETYLATED LANOLIN	E	Only for use in topical

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicines for dermal application.
331	ACETYLATED LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
332	ACETYLATED MONOGLYCERIDES	E	
333	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%.
334	ACETYLCYSTEINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.001%.
335	ACHILLEA ERBA-ROTTA SUBSP. MOSCHATA	A, H	
336	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 medicine must be no more

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 0.74 %.
337	ACHILLEA PTARMICA	A, H	
338	ACHYRANTHES ASPERA	A, H	
339	ACHYRANTHES BIDENTATA	A, H	
340	ACHYRANTHES FAURIEI	A, H	
341	ACID GREEN 25	E	Permitted for use only as a colour for topical use.
342	ACID RED 33	E	Permitted for use only as a colour for topical use.
343	ACID RED 87	E, H	Only for use as an active homoeopathic ingredient or for excipient use as a colour in topical medicines.
344	ACID TREATED WAXY MAIZE STARCH	E	
345	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%.
346	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			milligrams per pack.
347	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.
348	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.
349	ACONITUM NAPELLUS	A, H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum napellus. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
350	ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLAURATE 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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
351	ACRYLAMIDES COPOLYMER	E	Only for use in topical medicines for dermal application.
352	ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
353	ACRYLATES/ACRYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application.
354	ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
355	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%.
356	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%.
357	ACRYLATES/OCTYLACRYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
358	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%.
359	ACRYLATES/VA COPOLYMER	E	Only for use in topical medicines for dermal application.
360	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%.
361	ACTAEA CIMICIFUGA	A, H	
362	ACTAEA HERACLEIFOLIA	A, H	
363	ACTAEA PACHYPODA	A, H	
364	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			should stop using this product and see your doctor.'
365	ACTAEA SIMPLEX	A, H	
366	ACTAEA SPICATA	A, H	
367	ACTINIDIA CHINENSIS	A, H	
368	ACTINIDIA DELICIOSA	A, H	
369	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.
370	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).
371	ADEMETHIONINE DISULFATE DITOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate ditosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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)'
372	ADEMETIONINE DISULFATE TOSYLATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tosylate. 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 DISULFATE TRITOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tritosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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)'
374	ADEMETHIONINE HEXASULFATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine hexasulfate 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)'
375	ADEMETHIONINE 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-

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
376	ADEMETHIONINE 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 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)'
377	ADEMETHIONINE PENTATOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine pentatosylate 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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			the supervision of a healthcare practitioner (or words to that effect)'
378	ADEMETHIONINE TETRASULFATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine tetrasulfate 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)'
379	ADEMETHIONINE TETRATOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine tetratosylate 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)'

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
380	ADEMETIONINE 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)'
381	ADENOPHORA STRICTA	A, H	
382	ADENOPHORA TRIPHYLLA	A, H	
383	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%.
384	ADENOSINE 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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 0.1%.
385	ADENOSINE TRIPHOSPHATE	E	Only for use in topical medicines for dermal application.
386	ADENOSINE TRIPHOSPHATE DISODIUM	E	Only for use in topical medicines for dermal application.
387	ADIANTUM CAPILLUS-VENERIS	A, H	
388	ADIPIC ACID	E	
389	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%.
390	ADONIS VERNALIS	A, H	The concentration of equivalent dry Adonis vernalis in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
391	ADRENALINE (EPINEPHRINE)	H	Only for use as an active homoeopathic ingredient.
392	ADZUKI BEAN	E	
393	AEGOPodium PODAGRARIA	A, H	
394	AESCULUS CHINENSIS	A, H	
395	AESCULUS GLABRA	A, H	
396	AESCULUS HIPPOCASTANUM	A, H	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
397	AESCLUSUS X CARNEA	A, H	
398	AETHUSA CYNAPIUM	H	Only for use as an active homoeopathic ingredient.
399	AGAR	A, E	
400	AGASTACHE RUGOSA	A, H	
401	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%.
402	AGAVE AMERICANA	A, E, H	
403	AGRIMONIA EUPATORIA	A, E, H	
404	AGRIMONIA REPENS	A, H	
405	AGROSTIS TENUIS	A, H	
406	AILANTHUS ALTISSIMA	A, H	
407	AJUGA CHAMAEPITYS	A, H	
408	AJUGA REPTANS	A, H	
409	ALANINE	A, E	
410	ALANYLGLUTAMINE	A	Only for use in oral medicines.
411	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			300 micrograms of iodine per maximum recommended daily dose.
412	ALBIZIA JULIBRISSIN	A, H	
413	ALBIZIA LEBBECK	A, H	
414	ALCEA ROSEA	A, H	
415	ALCHEMILLA ALPINA	A, H	
416	ALCHEMILLA ARVENSIS	A, H	
417	ALCHEMILLA VULGARIS	A, H	
418	ALETRIS FARINOSA	A, H	
419	ALETRIS SPICATA	A, H	
420	ALEURITES MOLUCCANUS SEED OIL	E	Only for use in topical medicines for dermal application.
421	ALFADEX	A, E	Only for use in oral medicines. The maximum daily dose must provide no more than 6 g of alfadex.
422	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

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			on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
			When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
423	ALGINIC ACID	E	
424	ALISMA ORIENTALE	A, H	
425	ALISMA PLANTAGO AQUATICA	A, H	
426	ALKANNA TINCTORIA	A, H	
427	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%.
428	ALLANTOIN	E	Only for use in topical medicines for dermal application.
429	ALLIARIA PETIOLATA	A, H	
430	ALLIUM CEPA	A, H	
431	ALLIUM FISTULOSUM	A, H	
432	ALLIUM HIEROCHUNTINUM	A, H	

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433	ALLIUM MACROSTEMON	A, H	
434	ALLIUM ODORUM	A, H	
435	ALLIUM PORRUM	A, H	
436	ALLIUM SATIVUM	A, E, H	
437	ALLIUM SCHOENOPRASUM	A, H	
438	ALLIUM URSINUM	A, H	
439	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%.
440	ALLURA RED AC	E	Permitted for use only as a colour for oral and topical use.
441	ALLURA RED AC ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
442	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
443	ALLYL AMYL GLYCOLATE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
444	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%.
445	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 fragrance concentration in a medicine must be no more than 1%.
446	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

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Item	Ingredient name	Purpose	Specific requirements
			1%.
447	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 than 1%.
448	ALLYL HEPTYLATE	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%.
449	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 than 1%.
450	ALLYL ISOTHIOCYANATE	E	Permitted for use only in combination with other

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			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%.
451	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 flavour concentration in 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%.
452	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%.
453	ALMOND	E	
454	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

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			hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
455	ALNUS GLUTINOSA	A, H	
456	ALNUS INCANA SUBSP. RUGOSA	A, H	
457	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</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' [or words to that effect]. <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) 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	ALOE PERRYI	A, H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a

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			<p>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 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

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			<p>component(s)']; and</p> <ul style="list-style-type: none"> - (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'.
459	ALOE VERA	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 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';

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			<p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (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> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of 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> <p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not</p>

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

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			<p>requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' [or words to that effect]. <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) 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'.
461	ALOYSIA CITRODORA	A, H	
462	ALPHA CASOZEPINE ENRICHED HYDROLYSED MILK PROTEIN	A	<p>Only for use in oral medicines.</p> <p>The medicine requires the</p>

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			following warning statements on the medicine label: - (BABY3) 'Not suitable for use in children under the age of twelve months - except on professional advice' - (COWMK) 'Derived from cow's milk.'
463	ALPHA LIPOIC ACID	A	
464	ALPHA-2,2,6-TETRAMETHYL-CYCLOHEXENE BUTANAL	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%.
465	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 than 1%.
466	ALPHA-AMYL CINNAMYL 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

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			medicine must be no more than 5%.
467	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%.
468	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 than 1%.
469	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 flavour concentration in 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%.
470	ALPHA-FURFURYL OCTANOATE	E	Permitted for use only in

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			<p>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>
471	ALPHA- HEXYLCINNAMALDEHYDE	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 than 1%.</p>
472	ALPHA-IONOL	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 than 1%.</p>
473	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</p>

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
474	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>
475	ALPHA-ISO-METHYL 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>
476	ALPHA-METHYL ANISALACETONE	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>

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			medicine must be no more than 5%.
477	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%.
478	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%.
479	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 than 1%.
480	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

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			flavour concentration in 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%.
481	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%.
482	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%.
483	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%.
484	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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			<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>
485	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 than 1%.</p>
486	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 than 1%.</p>
487	ALPHA-SINENSAL	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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Item	Ingredient name	Purpose	Specific requirements
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
488	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 than 1%.
489	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 medicine must be no more than 1%.
490	ALPINIA GALANGA	A, H	
491	ALPINIA HAINANENSIS	A, H	
492	ALPINIA OFFICINARUM	A, H	
493	ALPINIA OXYPHYLLA	A, H	
494	ALSIDIUM HELMINTHOCHORTON	A, H	Iodine is a mandatory component of Alsidium

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			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.
495	ALSTONIA BOONEI	A, H	
496	ALSTONIA CONSTRICTA	H	Only for use as an active homoeopathic ingredient.
497	ALTERNANTHERA PHILOXEROIDES	A, H	
498	ALTEROMONAS FERMENT EXTRACT	E	Only for use in topical medicines for dermal application and not to be 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%.
499	ALTHAEA OFFICINALIS	A, E, H	
500	ALUM DODECAHYDRATE	A, E, H	
501	ALUMINIUM CHLOROHYDRATE	E	Only for use in topical medicines for dermal application.
502	ALUMINIUM CITRATE	E	Only for use in topical medicines for dermal application.

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503	ALUMINIUM DISTEARATE	E	Only for use in topical medicines for dermal application.
504	ALUMINIUM HYDROXIDE	E	Only for use in topical medicines for dermal application.
505	ALUMINIUM HYDROXIDE HYDRATE	E	Only for use in topical medicines for dermal application.
506	ALUMINIUM MAGNESIUM SILICATE	E	
507	ALUMINIUM MONOSTEARATE	E	Only for use in topical medicines for dermal application.
508	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.
509	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.
510	ALUMINIUM SODIUM SILICATE	E	When for oral or sublingual

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			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).’
511	ALUMINIUM STARCH OCTENYLSUCCINATE	E	The concentration in the medicine must be no more than 7%.
512	ALUMINIUM STEARATE	E	Only for use in topical medicines for dermal application.
513	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%.
514	AMARANTH	E	Permitted for use only as a colour for oral and topical use.
515	AMARANTH ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use
516	AMARANTHUS HYBRIDUS	A, H	
517	AMARANTHUS RETROFLEXUS	A, H	

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518	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%.
519	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%.
520	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 than 1%.
521	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%.

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522	AMBROSIA ARTEMISIIFOLIA	A, H	
523	AMBROSIA PSILOSTACHYA	A, H	
524	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%.
525	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%.
526	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%.
527	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%.
528	AMMONIA	E, H	Only for use as an active

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			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%.
529	AMMONIO METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
530	AMMONIUM ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
531	AMMONIUM ACRYLATES/ACRYLONITROGENS COPOLYMER	E	Only for use in topical medicines for dermal application.
532	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%.
533	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
534	AMMONIUM BICARBONATE	A, H	When used as an active ingredient, can only be supplied as an uncompound medicine substance packed for retail sale, and must comply with an uncompound substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
535	AMMONIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
536	AMMONIUM CARBONATE	E, H	Only for use as an active homoeopathic or excipient ingredient.
537	AMMONIUM CHLORIDE	A, E, H	Only for use as an active ingredient in homoeopathic medicines or as an uncompound medicine substance packed for retail sale. When used as an uncompound medicine substance the ingredient must comply with an uncompound 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.
538	AMMONIUM GLYCYRRHIZINATE	E	
539	AMMONIUM IODIDE	H	Only for use an active

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			ingredient in homoeopathic medicines.
540	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%.
541	AMMONIUM LAURETH SULFATE	E	Only for use in topical medicines for dermal application.
542	AMMONIUM LAURYL SULFATE	E	Only for use in topical medicines for dermal application.
543	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%.
544	AMMONIUM POLYACRYLOYLDIMETHYL TAURATE	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 3%.
545	AMMONIUM SULFIDE	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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%.
546	AMOMUM AROMATICUM	A, H	
547	AMOMUM VILLOSUM	A, H	
548	AMORPHOPHALLUS KONJAC	A, H	Only for use when the dosage form is not tablet.
549	AMPELODESMOS MAURITANICUS	A, H	
550	AMPELOPSIS JAPONICA	A, H	
551	AMYL ACETATE	E	Only for use in: - topical medicines for dermal application; or - combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
552	AMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
553	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%.
554	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%.
555	AMYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
556	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%.
557	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%.
558	AMYL 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 than 1%.
559	AMYL ISOBUTYRATE	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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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
560	AMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
561	AMYL 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%.
562	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%.
563	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%.
564	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%.
565	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%.
566	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 than 1%.
567	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
568	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>
569	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>
570	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 medicine must be no more than 5%.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
571	AMYRIS BALSAMIFERA	A, H	
572	AMYRIS OIL WEST INDIAN	A, E, H	
573	ANACARDIUM OCCIDENTALE	A, H	
574	ANACYCLUS PYRETHRUM	A, H	
575	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%.
576	ANAESTHETIC ETHER	H	Only for use as an active homoeopathic ingredient.
577	ANAGALLIS ARVENSIS	A, H	
578	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%.
579	ANANAS COMOSUS	A, E, H	
580	ANAPHALIS SINICA	A, H	
581	ANDROGRAPHIS PANICULATA	A, H	
582	ANEMARRHENA ASPHODELOIDES	A, E, H	
583	ANEMONE ALTAICA	A, H	
584	ANEMONE CHINENSIS	A, H	
585	ANEMONE HEPATICA	A, H	
586	ANEMONE PULSATILLA	A, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
587	ANEMONE RADDEANA	A, H	
588	ANETHOLE	E	
589	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%.
590	ANETHUM GRAVEOLENS	A, E, H	
591	ANGELICA ACUTILOBA	A, H	
592	ANGELICA ANOMALA	A, H	
593	ANGELICA ARCHANGELICA	A, E, H	
594	ANGELICA ATROPURPUREA	A, H	
595	ANGELICA DAHURICA	A, E, H	
596	ANGELICA DECURSIVA	A, H	
597	ANGELICA POLYMORPHA	A, E, H	
598	ANGELICA PUBESCENS	A, E, H	
599	ANGELICA ROOT DRY	A, H	
600	ANGELICA ROOT OIL	A, E, H	
601	ANGELICA SEED OIL	A, E, H	
602	ANGELICA STEM	E	
603	ANIBA ROSAEODORA	A, E, H	
604	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
605	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
606	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)'
607	ANISEED	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
608	ANISEED DRY	A, E, H	
609	ANISEED POWDER	A, E, H	
610	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%.
611	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 than 1%.
612	ANISYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in 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%.
613	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 than 1%.
614	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%.
615	ANNATTO	E	Permitted for use only as a colour for oral and topical use.
616	ANOGEISSUS LATIFOLIA	A, E, H	
617	ANTENNARIA DIOICA	A, E, H	
618	ANTHOCYANINS	E	
619	ANTHOXANTHUM ODORATUM	A, H	When used as an active ingredient, coumarin is a

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			mandatory component of Anthoxanthum odoratum and the concentration of coumarin in the medicine must be no more than 0.001%.
620	ANTHRISCUS CEREFOLIUM	A, H	
621	ANTHYLLIS VULNERARIA	A, H	
622	ANTIMONY POTASSIUM TARTRATE TRIHYDRATE	H	Only for use as an active homoeopathic ingredient.
623	ANTIMONY TRISULFIDE	H	Only for use as an active homoeopathic ingredient.
624	APIUM GRAVEOLENS	A, E, H	
625	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%.
626	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	H	Only for use as an active homoeopathic ingredient.
627	APPLE	E	
628	APPLE CIDER VINEGAR	E	
629	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%.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
630	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%.
631	APPLE FIBRE	E	
632	APRICOT	E	
633	APRICOT KERNEL OIL PEG-6 ESTERS	E	Only for use as an excipient in topical medicines for dermal application.
634	AQUILARIA MALACCENSIS	A, H	
635	AQUILARIA SINENSIS	A, H	
636	AQUILEGIA VULGARIS	A, H	
637	ARACHIDONIC ACID	E	Only for use in topical medicines for dermal application.
638	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%.
639	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			more than 0.5%.
640	ARACHIDYL PROPIONATE	E	Only for use in topical medicines for dermal application.
641	ARACHIS HYPOGAEA	A, E, H	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
642	ARACHIS OIL	A, E, H	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
643	ARALIA CORDATA	A, H	
644	ARALIA HISPIDA	A, H	
645	ARALIA NUDICAULIS	A, H	
646	ARALIA RACEMOSA	A, H	
647	ARCTIUM LAPPA	A, E, H	
648	ARCTIUM MINUS	A, H	
649	ARCTOSTAPHYLOS UVA-URSI	A, E, H	Arbutin is a mandatory component of Arctostaphylos uva-ursi. 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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 0.74 %.
650	ARDISIA JAPONICA	A, H	
651	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%.
652	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.
653	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.'
654	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 0.05%.
655	ARISAEMA ATRORUBENS	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
656	ARISAEMA CONSANGUINEUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
657	ARISAEMA JAPONICUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
658	ARMORACIA RUSTICANA	A, E, H	<p>Volatile oil components (of <i>Armoracia rusticana</i>) is a mandatory component of <i>Armoracia rusticana</i>.</p> <p>The maximum recommended daily dose must contain no more than 20 mg of volatile oil components (of <i>Armoracia rusticana</i>).</p>
659	ARNEBIA EUCHROMA	A, H	
660	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> .
661	ARNICA MOLLIS	A, H	When for use other than topically on unbroken skin, the maximum recommended

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			daily dose must be no more than the equivalent of 1mg of the dry herbal material.
662	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 arnica montana.
663	ARRHENATHERUM ELATIUS	A, H	
664	ARROWROOT	A, E, H	
665	ARSENIC TRIIODIDE	H	Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than 0.001%.
666	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%.
667	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%.
668	ARTEMISIA ABSINTHIUM	A, H	Thujone is a mandatory component of Artemisia absinthium. The concentration of thujone

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			from <i>Artemisia absinthium</i> in the medicine must be no more than 4%.
669	ARTEMISIA ANNUA	A, H	Thujone is a mandatory component of <i>Artemisia annua</i> . The concentration of thujone from <i>Artemisia annua</i> in the medicine must be no more than 4%.
670	ARTEMISIA ARBORESCENS	A, H	Thujone is a mandatory component of <i>Artemisia arborescens</i> . The concentration of thujone from <i>Artemisia arborescens</i> in the medicine must be no more than 4%.
671	ARTEMISIA ARGYI	A, H	Thujone is a mandatory component of <i>Artemisia argyi</i> . The concentration of thujone from <i>Artemisia argyi</i> in the medicine must be no more than 4%.
672	ARTEMISIA DRACUNCULUS	A, E, H	Thujone is a mandatory component of <i>Artemisia dracunculus</i> . The concentration of thujone from <i>Artemisia dracunculus</i> in the medicine must be no more than 4%.
673	ARTEMISIA FRIGIDA	A, H	Thujone is a mandatory component of <i>Artemisia frigida</i> . The concentration of thujone

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			from <i>Artemisia frigida</i> in the medicine must be no more than 4%.
674	ARTEMISIA HERBA-ALBA	A, H	<p>Thujone is a mandatory component of <i>Artemisia herba-alba</i>.</p> <p>The concentration of thujone from <i>Artemisia herba-alba</i> in the medicine must be no more than 4%.</p>
675	ARTEMISIA MARITIMA	A, H	<p>Thujone is a mandatory component of <i>Artemisia maritima</i>.</p> <p>The concentration of thujone from <i>Artemisia maritima</i> in the medicine must be no more than 4%.</p>
676	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 than 1%.</p>
677	ARTEMISIA PALLENS	A, E, H	<p>Thujone is a mandatory component of <i>Artemisia pallens</i>.</p> <p>The concentration of thujone from <i>Artemisia pallens</i> in the</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 4%.
678	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%.
679	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%.
680	ARTERY	H	Only for use as an active homoeopathic ingredient.
681	ARTHROSPIRA MAXIMA	A, E, H	
682	ARTHROSPIRA PLATENSIS	A, E, H	
683	ARUM MACULATUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
684	ASAFOETIDA GUM	A, H	
685	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			than 5%.
686	ASARUM EUROPAEUM	A, H	
687	ASARUM HETEROTROPOIDES	A, H	
688	ASARUM OIL	E	
689	ASARUM SIEBOLDII	A, E, H	
690	ASCLEPIAS TUBEROSA	A, H	
691	ASCOPHYLLUM NODOSUM	A, E, H	<p>Iodine is a mandatory component of <i>Ascophyllum nodosum</i>.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
692	ASCORBIC ACID	A, E	
693	ASCORBYL GLUCOSIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p>
694	ASCORBYL METHYLSILANOL PECTINATE	E	<p>Only for use in topical medicines for dermal application.</p>

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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
695	ASCORBYL PALMITATE	A, E	When for oral use, the maximum recommended daily dose must contain no more than 100mg of ascorbyl palmitate.
696	ASCORBYL TOCOPHERYL MALEATE	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 0.0575%.
697	ASPALATHUS LINEARIS	A, E, H	
698	ASPARAGINE	A, E	
699	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%.
700	ASPARAGUS	E, H	Only for use as an active homoeopathic or excipient ingredient.
701	ASPARAGUS COCHINCHINENSIS	A, H	
702	ASPARAGUS OFFICINALIS	A, E, H	
703	ASPARAGUS RACEMOSUS	A, H	The plant part must be dried, peeled root, and water extracts or ethanol/water extracts (containing up to 45%

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			ethanol) of the dried, peeled root.
704	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'
705	ASPARTIC ACID	A, E	
706	ASPERGILLUS ORYZAE	A, E, H	
707	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).
708	ASTER NOVI-BELGII	A, H	
709	ASTER TATARICUS	A, H	
710	ASTRAGALUS ADSURGENS	A, H	
711	ASTRAGALUS COMPLANATUS	A, H	
712	ASTRAGALUS EXCARPUS	A, H	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
713	ASTRAGALUS GUMMIFER	A, E, H	
714	ASTRAGALUS LENTIGINOSUS	A, H	
715	ASTRAGALUS MEMBRANACEUS	A, E, H	
716	ASTRAGALUS PENDULIFLORUS	A, H	
717	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%.
718	ATRACTYLODES JAPONICA	A, H	
719	ATRACTYLODES LANCEA	A, H	
720	ATRACTYLODES MACROCEPHALA	A, H	
721	ATROPA BELLADONNA	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Atropa belladonna. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
722	ATROPINE SULFATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
723	ATTALEA SPECIOSA	E	Only for use in topical medicines for dermal application.
724	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%.
725	AUREOBASIDIUM PULLULANS	A, H	
726	AVENA FATUA	A, H	Gluten is a mandatory component of Avena fatua when the plant part is seed and the route of administration is other than topical and mucosal.
727	AVENA SATIVA	A, E, H	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.
728	AVOCADO	E	
729	AVOCADO OIL	E	
730	AVOCADO OIL UNSAAPONIFIABLES	E	Only for use in topical medicines for dermal application.
731	AZADIRACHTA INDICA	A, H	The ingredient can only be derived from the plant part seed and must be cold pressed

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>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).'
732	AZOVAN BLUE	E	Permitted for use only as a colour for topical use.
733	AZULENE	E	Only for use in topical medicines for dermal application.