Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2020

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

Dated 27 May 2020

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

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1 Name

This instrument is the *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2020*.

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	8 June 2020.	8 June 2020

Note: This table relates only to the provisions of this instrument as originally made.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 Pharmacopeia-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

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	(+-)-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%.
2	(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%.
3	(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%.
4	(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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			excipient formulation in a medicine must be no more than 1%.
5	(5Z)-3-METHYL-5-CYCLOTETRADECEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
6	(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%.
7	(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%.
8	(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

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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
9	(S)-LACTIC ACID	A, E, H	
10	(S)-S-ADENOSYLMETHIONINE DISULFATE DITOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (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)'
11	(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-

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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)'
12	(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 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)'
13	(S)-S-ADENOSYLMETHIONINE HEXASULFATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine hexasulfate 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
14	(S)-S-ADENOSYLMETHIONINE HEXATOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine hexatosylate dihydrate and must be declared in the application. (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)'
15	(S)-S-ADENOSYLMETHIONINE PENTASULFATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine pentasulfate 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
16	(S)-S-ADENOSYLMETHIONINE PENTATOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine pentatosylate 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)'
17	(S)-S-ADENOSYLMETHIONINE TETRASULFATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine tetrasulfate 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			practitioner (or words to that effect)'
18	(S)-S-ADENOSYLMETHIONINE TETRATOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine tetratosylate 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	(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)'

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
20	(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%.
21	(Z, Z)-3,6-NONADIEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
22	1,1,1-TRICHLOROETHANE	E	The concentration in the medicine must be no more than 25%.
23	1,2,3,4,4A,5,8,8A-OCTAHYDRO-2,2,6,8-TETRAMETHYL-1-NAPHTHALENOL	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%.
24	1,2-HEXANEDIOL	E	Only for use in topical

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
25	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%.
26	1,3,5-UNDECATRIENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
27	1,3-BUTYLENE GLYCOL	E	
28	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
29	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%.
30	1,4-CINEOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%
31	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%.
32	1,5,9-TRIMETHYL-13-OXABICYCLO[10.1.0]TRIDECA-4,8-	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	DIENE		fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
33	1,7,7-TRIMETHYLBICYCLO[4.4.0]DECAN-3-YL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
34	1-(2,2,6-TRIMETHYLCYCLOHEXYL)-3-HEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
35	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%.
36	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

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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%.
37	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%.
38	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 medicine must be no more than 1%.
39	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%.
40	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

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 1%.
41	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%.
42	1-METHOXY-4-PROPENYLBENZENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
43	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%.
44	1-METHYL-3-(2-METHYLPROPYL)-CYCLOHEXANOL	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%.
45	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%.
46	1-OCTEN-3-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
47	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%.
48	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

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%.
49	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%.
50	10-UNDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
51	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%.
52	2,2,3-TRIMETHYLCYCLOPENT-3-ENE-1-ETHYL ACETATE	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%.
53	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%.
54	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%.
55	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%.
56	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

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%.
57	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%.
58	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%.
59	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%.
60	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
61	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%.
62	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%.
63	2,3-DIHYDRO-2,5-DIMETHYL-1H-INDENE-2-METHANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
64	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
65	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%.
66	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%.
67	2,3-PENTANEDIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
68	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
69	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%.
70	2,4-DECADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 3 mg of 2,4-Decadienal.
71	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%.
72	2,4-DIMETHYL THIAZOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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%.
73	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%.
74	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%.
75	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%.
76	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

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**
			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.
77	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.
78	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%.
79	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

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%.
80	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%.
81	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 medicine must be no more than 1%.
82	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%.
83	2,5-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as 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**
			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 1%. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
84	2,6,6,TRIMETHYL-2-CYCLOHEXENE-1,4-DIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
85	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%.
86	2,6-DIMETHOXYPHENOL	E	Permitted for use only in

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%.
87	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%.
88	2,6-DIMETHYL-2-HEPTENAL-(7)	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
89	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%.

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**
90	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%.
91	2,6-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
92	2,6-NONADIEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
93	2,6-OCTADIENOIC ACID, 3,7-DIMETHYL-, METHYL ESTER, (2E)-	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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%.
94	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%.
95	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%.
96	2-(2-METHYLPHENYL)ETHANOL	E	Permitted for use only in combination with other 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%.
97	2-[(3,7-DIMETHYL-6-OCTEN-1-YLIDENE)AMINO]BENZOIC ACID,	E	Permitted for use only in combination with other permitted ingredients as 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**
	METHYL ESTER		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-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%.
99	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%.
100	2-ACETYLFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
101	2-ACETYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

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 5%.
102	2-ACETYLPYRIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
103	2-AMINO-2-METHYL-1-PROPANOL	E	Only for use in topical medicines for dermal application.
104	2-BENZYL-4,4,6-TRIMETHYL-1,3-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
105	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%.

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**
106	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%.
107	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%.
108	2-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
109	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
110	2-DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
111	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%.
112	2-ETHOXYETHANOL	E	The residual solvent limit for 2-Ethoxyethanol is 1.6 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.016%.
113	2-ETHYL-1-HEXANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

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 5%.
114	2-ETHYL-3,5-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
115	2-ETHYL-3,6-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
116	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%.

Permissible ingredients and requirements

Column 1	Column 2	Column 3	Column 4
Item	**Ingredient name**	**Purpose**	**Specific requirements**
117	2-ETHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-2-BUTEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
118	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%.
119	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%.
120	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%.

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**
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
121	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%.
122	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%.
123	2-HEPTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
124	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

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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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
125	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%.
126	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 1%.
127	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%.

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**
128	2-ISOBUTYL-3-METHOXYPYRAZINE	E	Permitted for use only in combination with 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-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%.
130	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%.
131	2-ISOPROPYL-4-METHYLTHIAZOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
132	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%.
133	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%.
134	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%.
135	2-METHYL BUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more

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**
			1%.
136	2-METHYL HEPTANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
137	2-METHYL-2-PENTENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
138	2-METHYL-2-VINYL-5-ISOPROPENYLTETRAHYDROFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
139	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
140	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%.
141	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%.
142	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%.
143	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%.

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**
144	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%.
145	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.
146	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%.
147	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
148	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%.
149	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%.
150	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%.
151	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%.

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**
152	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%.
153	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%.
154	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%.
155	2-METHYLDECANAL	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%.
156	2-METHYLHEXANOIC ACID	E	Permitted for use only in combination with other

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%.
157	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 1%.
158	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%.
159	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

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 1%.
160	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%.
161	2-NONENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
162	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%.
163	2-OXOBUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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%.
164	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%.
165	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%.
166	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%.
167	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

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**
			than 5%.
168	2-PENTYL FURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
169	2-PHENYLPROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
170	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
171	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%.
172	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%.
173	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%.
174	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%.

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**
175	2-TRANS-6-CIS-NONADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
176	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%.
177	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 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
178	2-TRIDECENENITRILE	E	Permitted for use only in combination with 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	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%.
180	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%.
181	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%.
182	3,4,4A,5,8,8A-HEXAHYDRO-3',7-DIMETHYLSPIRO-1,4-	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**
	METHANONAPHALENE-2(1H),2'-OXIRANE		permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
183	3,4-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%.
184	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%.
185	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%.
186	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

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%.
187	3,5-DIMETHOXYTOLUENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
188	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%.
189	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%.
190	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

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**
			than 1%.
191	3,7-DIMETHYL-1-OCTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
192	3,7-DIMETHYL-1-OCTEN-3-OL	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%.
193	3,7-DIMETHYL-2,6-NONADIENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
194	3,7-DIMETHYL-2,6-OCTADIENAL REACTION PRODUCTS WITH ETHANOL	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.

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 not be more than 1%.
195	3,7-DIMETHYL-7-METHOXYOCTAN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
196	3-(3-ISOPROPYLPHENYL)BUTANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
197	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%.
198	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

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**
			than 5%.
199	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%.
200	3-(ISO-CAMPHYL-5)-CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
201	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%.
202	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
203	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%.
204	3-ETHYLPYRIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
205	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%.
206	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%.

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**
207	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 1%.
208	3-ISO-CAMPHYL-5-CYCLOHEXAN-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%.
209	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%.
210	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 1%.
211	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%.
212	3-METHYL-5-PHENYL PENT-2-ENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
213	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%.
214	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
215	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%.
216	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%.
217	3-METHYLCYCLOPENTADECANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
218	3-METHYLCYCLOPENTADECENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
219	3-METHYLTHIOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a

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%.
220	3-OCTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
221	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%.
222	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%.

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**
223	3-PHENYLPROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
224	3-PHENYLPROPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
225	3-PHENYLPROPYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
226	3-PROPYLIDENE PHTHALIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
227	3-TRANS-ISOCAMPHYLCYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
228	3A,6,6,9A-TETRAMETHYLDODECAHYDRONAPHTHO[2,1-B] FURAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
229	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%.
230	4,4A,5,9B-TETRAHYDROINDENO(1,2-D)-1,3-	E	Permitted for use only in combination with other permitted ingredients as a

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**
	DIOXIN		fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
231	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%.
232	4,7-METHANO-1H-INDENEMETHANOL, OCTAHYDRO-, ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
233	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%.
234	4,8-DIMETHYL-3,7-NONADIEN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a

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%.
235	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%. A medicine that contains the ingredient must not be listed in the Register on or after 2 March 2020 or be supplied after 2 March 2021.
236	4-(4-METHYL-3-PENTEN-1-YL)-3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
237	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

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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%.
238	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%.
239	4-(PARA-HYDROXYPHENYL)-2-BUTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
240	4-(PARA-METHOXYPHENYL)-2-BUTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
241	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%.
242	4-CYCLOHEXYL-2-METHYL-2-BUTANOL	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%.
243	4-ETHYL GUAIACOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
244	4-HEPTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more

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**
			than 5%.
245	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%.
246	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%.
247	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%.
248	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**
249	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%.
250	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%.
251	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%.
252	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 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
253	4-METHYLBENZYLIDENE CAMPHOR	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 4%. The following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
254	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%.
255	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
256	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%.
257	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%.
258	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%.
259	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
260	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%.
261	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%.
262	5,7-DIHYDRO-2-METHYLTHIENO (3,4D) PYRIMIDINE	E	Permitted for use only in combination with 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-(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%.
264	5-ACETYL-1,1,2,3,3,6-	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**
	HEXAMETHYL INDAN		combination with other permitted ingredients 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%.
265	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%.
266	5-ETHYL-3-HYDOXY-4-METHYL-2(5H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
267	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
268	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%.
269	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%.
270	5-METHYL 2-PHENYL HEXEN-2-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
271	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%.
272	5-METHYL-3-BUTYLTETRAHYDROPYRAN-4-	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	YL ACETATE		fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
273	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%.
274	5-PENTYL-2(5H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
275	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%.
276	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

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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%.
277	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%.
278	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%.
279	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%.
280	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
281	6-METHYL COUMARIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
282	6-METHYL-2-BUTEN-3-OL-2	E	
283	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
284	7-METHYL-2H-1,5-BENZODIOXEPIN-3(4H)-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
285	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%.
286	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%.
287	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 1%.
288	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%.
289	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%.
290	9-DECEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
291	ABELMOSCHUS MOSCHATUS	A, H	
292	ABELMOSCHUS MOSCHATUS SUBSP. MOSCHATUS	A, H	
293	ABIES BALSAMEA	A, H	
294	ABIES NIGRA	A, H	
295	ABIES PECTINATA	A, H	
296	ABIES SIBIRICA	A, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
297	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.
298	ABUTILON THEOPHRASTI	A, H	
299	ACACIA	A, E, H	
300	ACACIA BAILEYANA	A, H	
301	ACACIA CATECHU	A, H	
302	ACACIA DEALBATA	A, H	
303	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%.
304	ACACIA FARNESIANA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
305	ACACIA LONGIFOLIA	A, E, H	
306	ACACIA NILOTICA	A, E, H	
307	ACACIA SENEGAL	A, E, H	
308	ACALYPHA INDICA	A, H	
309	ACANTHUS MOLLIS	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
310	ACER CAMPESTRE	A, H	
311	ACER NEGUNDO	A, H	
312	ACER SACCHARINUM	A, H	
313	ACER SACCHARUM	A, E, H	
314	ACEROLA	E	
315	ACESULFAME POTASSIUM	E	
316	ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
317	ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
318	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

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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%.
319	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%.
320	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%.
321	ACETANISOLE	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
322	ACETIC ACID	E, H	The concentration in the medicine must be no more

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 80%.
323	ACETOIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
324	ACETOMENAPHTHONE	A, E	
325	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%.
326	ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
327	ACETOVANILLONE	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. Permitted for use only in combination with other permitted ingredients as a fragrance. If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.
328	ACETOXYDIHYDRODICYCLOPENTADIENE	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%.
329	ACETYL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
330	ACETYL DIPEPTIDE-1 CETYL ESTER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
331	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'
332	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%.
333	ACETYL LEVOCARNITINE HYDROCHLORIDE	A, E	
334	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%.
335	ACETYLATED LANOLIN	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
336	ACETYLATED LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
337	ACETYLATED MONOGLYCERIDES	E	
338	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%.
339	ACETYLCYSTEINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.001%.
340	ACHILLEA ERBA-ROTTA SUBSP. MOSCHATA	A, H	
341	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 than 0.74 %.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
342	ACHILLEA PTARMICA	A, H	
343	ACHYRANTHES ASPERA	A, H	
344	ACHYRANTHES BIDENTATA	A, H	
345	ACHYRANTHES FAURIEI	A, H	
346	ACID GREEN 25	E	Permitted for use only as a colour for topical use.
347	ACID RED 33	E	Permitted for use only as a colour for topical use.
348	ACID RED 87	E, H	Only for use as an active homoeopathic ingredient or for excipient use as a colour in topical medicines.
349	ACID TREATED WAXY MAIZE STARCH	E	
350	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%.
351	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.
352	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.
353	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.
354	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.
355	ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.7%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
356	ACRYLAMIDES COPOLYMER	E	Only for use in topical medicines for dermal application.
357	ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
358	ACRYLATES/ACRYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application.
359	ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
360	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%.
361	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%.
362	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**
363	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%.
364	ACRYLATES/VA COPOLYMER	E	Only for use in topical medicines for dermal application.
365	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%.
366	ACTAEA CIMICIFUGA	A, H	
367	ACTAEA HERACLEIFOLIA	A, H	
368	ACTAEA PACHYPODA	A, H	
369	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
370	ACTAEA SIMPLEX	A, H	
371	ACTAEA SPICATA	A, H	
372	ACTINIDIA CHINENSIS	A, H	
373	ACTINIDIA DELICIOSA	A, H	
374	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.
375	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).
376	ADEMETIONINE DISULFATE DITOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			ditosylate 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	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)'
378	ADEMETIONINE DISULFATE TRITOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tritosylate dihydrate. Ademetionine in the form of

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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	ADEMETIONINE 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)'
380	ADEMETIONINE HEXATOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine hexatosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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	ADEMETIONINE PENTASULFATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine pentasulfate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning 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)'
382	ADEMETIONINE 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

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)'
383	ADEMETIONINE 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)'
384	ADEMETIONINE 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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)'
385	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)'
386	ADENOPHORA STRICTA	A, H	
387	ADENOPHORA TRIPHYLLA	A, H	
388	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
389	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 than 0.1%.
390	ADENOSINE TRIPHOSPHATE	E	Only for use in topical medicines for dermal application.
391	ADENOSINE TRIPHOSPHATE DISODIUM	E	Only for use in topical medicines for dermal application.
392	ADIANTUM CAPILLUS-VENERIS	A, H	
393	ADIPIC ACID	E	
394	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%.
395	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%.
396	ADRENALINE (EPINEPHRINE)	H	Only for use as an active homoeopathic ingredient.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
397	ADZUKI BEAN	E	
398	AEGOPODIUM PODAGRARIA	A, H	
399	AESCULUS CHINENSIS	A, H	
400	AESCULUS GLABRA	A, H	
401	AESCULUS HIPPOCASTANUM	A, H	
402	AESCULUS X CARNEA	A, H	
403	AETHUSA CYNAPIUM	H	Only for use as an active homoeopathic ingredient.
404	AGAR	A, E	
405	AGASTACHE RUGOSA	A, H	
406	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%.
407	AGAVE AMERICANA	A, E, H	
408	AGRIMONIA EUPATORIA	A, E, H	
409	AGRIMONIA REPENS	A, H	
410	AGROSTIS TENUIS	A, H	
411	AILANTHUS ALTISSIMA	A, H	
412	AJUGA CHAMAEPITYS	A, H	
413	AJUGA REPTANS	A, H	
414	ALANINE	A, E	
415	ALANYLGLUTAMINE	A	Only for use in oral medicines.
416	ALARIA ESCULENTA	A, H	Iodine is a mandatory component of Alaria

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			esculenta. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
417	ALBIZIA JULIBRISSIN	A, H	
418	ALBIZIA LEBBECK	A, H	
419	ALCEA ROSEA	A, H	
420	ALCHEMILLA ALPINA	A, H	
421	ALCHEMILLA ARVENSIS	A, H	
422	ALCHEMILLA VULGARIS	A, H	
423	ALETRIS FARINOSA	A, H	
424	ALETRIS SPICATA	A, H	
425	ALEURITES MOLUCCANUS SEED OIL	E	Only for use in topical medicines for dermal application.
426	ALFADEX	A, E	Only for use in oral medicines. The maximum daily dose must provide no more than 6 g of alfadex.
427	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

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			daily dose must be no more than 13.5 g. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' 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).
428	ALGINIC ACID	E	
429	ALISMA ORIENTALE	A, H	
430	ALISMA PLANTAGO AQUATICA	A, H	
431	ALKANNA TINCTORIA	A, H	
432	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%.
433	ALLANTOIN	E	Only for use in topical

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines for dermal application.
434	ALLIARIA PETIOLATA	A, H	
435	ALLIUM CEPA	A, H	
436	ALLIUM FISTULOSUM	A, H	
437	ALLIUM HIEROCHUNTINUM	A, H	
438	ALLIUM MACROSTEMON	A, H	
439	ALLIUM ODORUM	A, H	
440	ALLIUM PORRUM	A, H	
441	ALLIUM SATIVUM	A, E, H	
442	ALLIUM SCHOENOPRASUM	A, H	
443	ALLIUM URSINUM	A, H	
444	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%.
445	ALLURA RED AC	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
446	ALLURA RED AC ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
447	ALLYL ALPHA-IONONE	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**
			If used in a flavour 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%.
448	ALLYL AMYL GLYCOLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
449	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%.
450	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 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
451	ALLYL CYCLOHEXYLOXYACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
452	ALLYL HEPTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
453	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%.
454	ALLYL HEXANOATE	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%.
455	ALLYL ISOTHIOCYANATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
456	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 1%.
457	ALLYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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%.
458	ALMOND	E	
459	ALMOND OIL	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Almond oil. The concentration of Amygdalin in the medicine must be 0%. The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
460	ALNUS GLUTINOSA	A, H	
461	ALNUS INCANA SUBSP. RUGOSA	A, H	
462	ALOE FEROX	A, E, H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe ferox. 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';

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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
463	ALOE PERRYI	A, H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe perryi. 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].

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' [or words to that effect]. When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
464	ALOE VERA	A, E, H	When the route of administration is oral or

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

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
465	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect]. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' [or words to that effect]. When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
466	ALOYSIA CITRODORA	A, H	
467	ALPHA CASOZEPINE ENRICHED HYDROLYSED MILK PROTEIN	A	Only for use in oral medicines. The medicine requires the 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.'
468	ALPHA LIPOIC ACID	A	
469	ALPHA-2,2,6-TETRAMETHYL-CYCLOHEXENEBUTANAL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
470	ALPHA-AMYL	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	CINNAMALDEHYDE		combination with other permitted ingredients 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%.
471	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 medicine must be no more than 5%.
472	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%.
473	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

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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 1%.
474	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 1%.
475	ALPHA-FURFURYL OCTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
476	ALPHA-HEXYLCINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
477	ALPHA-IONOL	E	Permitted for use only in combination with other permitted ingredients 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%.
478	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 1%.
479	ALPHA-IRONE	E	Permitted for use only in combination with other permitted ingredients 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			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
480	ALPHA-ISO-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
481	ALPHA-METHYL ANISALACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
482	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%.
483	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 5%.
484	ALPHA-METHYL BUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
485	ALPHA-METHYL CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
486	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%.
487	ALPHA-METHYL NAPHTHYL	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**
	KETONE		combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
488	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%.
489	ALPHA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
490	ALPHA-PHELLANDRENE	E	Permitted for use only in combination with other permitted ingredients 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

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 1%.
491	ALPHA-PINENE	E	Permitted for use only in combination with other permitted ingredients 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%.
492	ALPHA-SINENSAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
493	ALPHA-TERPINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
494	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 1%.
495	ALPINIA GALANGA	A, H	
496	ALPINIA HAINANENSIS	A, H	
497	ALPINIA OFFICINARUM	A, H	
498	ALPINIA OXYPHYLLA	A, H	
499	ALSIDIUM HELMINTHOCHORTON	A, H	Iodine is a mandatory component of Alsidium helminthochorton. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
500	ALSTONIA BOONEI	A, H	
501	ALSTONIA CONSTRICTA	H	Only for use as an active homoeopathic ingredient.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
502	ALTERNANTHERA PHILOXEROIDES	A, H	
503	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%.
504	ALTHAEA OFFICINALIS	A, E, H	
505	ALUM DODECAHYDRATE	A, E, H	
506	ALUMINIUM CHLOROHYDRATE	E	Only for use in topical medicines for dermal application.
507	ALUMINIUM CITRATE	E	Only for use in topical medicines for dermal application.
508	ALUMINIUM DISTEARATE	E	Only for use in topical medicines for dermal application.
509	ALUMINIUM HYDROXIDE	E	Only for use in topical medicines for dermal application.
510	ALUMINIUM HYDROXIDE HYDRATE	E	Only for use in topical medicines for dermal application.
511	ALUMINIUM MAGNESIUM SILICATE	E	

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
512	ALUMINIUM MONOSTEARATE	E	Only for use in topical medicines for dermal application.
513	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.
514	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.
515	ALUMINIUM SODIUM SILICATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
516	ALUMINIUM STARCH OCTENYLSUCCINATE	E	The concentration in the medicine must be no more than 7%.

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
517	ALUMINIUM STEARATE	E	Only for use in topical medicines for dermal application.
518	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%.
519	AMARANTH	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
520	AMARANTH ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use
521	AMARANTHUS HYBRIDUS	A, H	
522	AMARANTHUS RETROFLEXUS	A, H	
523	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%.
524	AMBRETTE SEED OIL	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			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%.
525	AMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
526	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%.
527	AMBROSIA ARTEMISIIFOLIA	A, H	
528	AMBROSIA PSILOSTACHYA	A, H	
529	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%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
530	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%.
531	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%.
532	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%.
533	AMMONIA	E, H	Only for use as an active homoeopathic or excipient ingredient. When used as an excipient ingredient, the medicine is only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
534	AMMONIO METHACRYLATE	E	Only for use in oral

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
	COPOLYMER		medicines.
535	AMMONIUM ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
536	AMMONIUM ACRYLATES/ACRYLONITROGENS COPOLYMER	E	Only for use in topical medicines for dermal application.
537	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%.
538	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%.
539	AMMONIUM BICARBONATE	A, H	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
540	AMMONIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
541	AMMONIUM CARBONATE	E, H	Only for use as an active homoeopathic or excipient ingredient.
542	AMMONIUM CHLORIDE	A, E, H	Only for use as an active ingredient in homoeopathic medicines or as an uncompounded medicine substance packed for retail sale. When used as an uncompounded medicine substance the ingredient must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. If used as an excipient ingredient then the medicine is only for topical use for dermal application.
543	AMMONIUM GLYCYRRHIZINATE	E	
544	AMMONIUM IODIDE	H	Only for use an active ingredient in homoeopathic medicines.
545	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

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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%.
546	AMMONIUM LAURETH SULFATE	E	Only for use in topical medicines for dermal application.
547	AMMONIUM LAURYL SULFATE	E	Only for use in topical medicines for dermal application.
548	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%.
549	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%.
550	AMMONIUM SULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
551	AMOMUM AROMATICUM	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
552	AMOMUM VILLOSUM	A, H	
553	AMORPHOPHALLUS KONJAC	A, H	Only for use when the dosage form is not tablet.
554	AMPELODESMOS MAURITANICUS	A, H	
555	AMPELOPSIS JAPONICA	A, H	
556	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%.
557	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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
558	AMYL BENZOATE	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%.
559	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%.
560	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%.
561	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
562	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%.
563	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 1%.
564	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%.
565	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

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**
			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
566	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%.
567	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%.
568	AMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
569	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

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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%.
570	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%.
571	AMYL VINYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
572	AMYL VINYL CARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a 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**
573	AMYLASE	A	Amylase must be derived from Aspergillus oryzae, and comply with the relevant compositional guideline. When used in a divided preparation, the allowed unit is Alpha-amylase dextrinising unit or Thousand alpha-amylase dextrinising unit. When used as an undivided preparation, the allowed unit is Thousand alpha-amylase dextrinising unit per gram or Dextrinising unit per gram.
574	AMYLCYCLOHEXYL ACETATE (MIXED ISOMERS)	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
575	AMYLOPECTIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
576	AMYRIS BALSAMIFERA	A, H	
577	AMYRIS OIL WEST INDIAN	A, E, H	
578	ANACARDIUM OCCIDENTALE	A, H	
579	ANACYCLUS PYRETHRUM	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
580	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%.
581	ANAESTHETIC ETHER	H	Only for use as an active homoeopathic ingredient.
582	ANAGALLIS ARVENSIS	A, H	
583	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%.
584	ANANAS COMOSUS	A, E, H	
585	ANAPHALIS SINICA	A, H	
586	ANDROGRAPHIS PANICULATA	A, H	The following warning statement is required on the label: - (ANDROG) ‘Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis) stop use and seek immediate medical attention’ (or words to that effect).
587	ANEMARRHENA ASPHODELOIDES	A, E, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
588	ANEMONE ALTAICA	A, H	
589	ANEMONE CHINENSIS	A, H	
590	ANEMONE HEPATICA	A, H	
591	ANEMONE PULSATILLA	A, H	
592	ANEMONE RADDEANA	A, H	
593	ANETHOLE	E	
594	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%.
595	ANETHUM GRAVEOLENS	A, E, H	
596	ANGELICA ACUTILOBA	A, H	
597	ANGELICA ANOMALA	A, H	
598	ANGELICA ARCHANGELICA	A, E, H	
599	ANGELICA ATROPURPUREA	A, H	
600	ANGELICA DAHURICA	A, E, H	
601	ANGELICA DECURSIVA	A, H	
602	ANGELICA POLYMORPHA	A, E, H	
603	ANGELICA PUBESCENS	A, E, H	
604	ANGELICA ROOT DRY	A, H	
605	ANGELICA ROOT OIL	A, E, H	
606	ANGELICA SEED OIL	A, E, H	
607	ANGELICA STEM	E	
608	ANIBA ROSAEODORA	A, E, H	
609	ANISALDEHYDE	E	Permitted for use only in combination with other

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 1%.
610	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%.
611	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:

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (CHILD) 'Keep out of reach of children (or word to that effect)'
612	ANISEED	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
613	ANISEED DRY	A, E, H	
614	ANISEED POWDER	A, E, H	
615	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%.
616	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
617	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 flavour concentration in 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%.
618	ANISYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
619	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
620	ANNATTO	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
621	ANOGEISSUS LATIFOLIA	A, E, H	
622	ANTENNARIA DIOICA	A, E, H	
623	ANTHOCYANINS	E	
624	ANTHOXANTHUM ODORATUM	A, H	When used as an active ingredient, coumarin is a mandatory component of Anthoxanthum odoratum and the concentration of coumarin in the medicine must be no more than 0.001%.
625	ANTHRISCUS CEREFOLIUM	A, H	
626	ANTHYLLIS VULNERARIA	A, H	
627	ANTIMONY POTASSIUM TARTRATE TRIHYDRATE	H	Only for use as an active homoeopathic ingredient.
628	ANTIMONY TRISULFIDE	H	Only for use as an active homoeopathic ingredient.
629	APIUM GRAVEOLENS	A, E, H	
630	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%.
631	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	H	Only for use as an active homoeopathic ingredient.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
632	APPLE	E	
633	APPLE CIDER VINEGAR	E	
634	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%.
635	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%.
636	APPLE FIBRE	E	
637	APRICOT	E	
638	APRICOT KERNEL OIL PEG-6 ESTERS	E	Only for use as an excipient in topical medicines for dermal application.
639	AQUILARIA MALACCENSIS	A, H	
640	AQUILARIA SINENSIS	A, H	
641	AQUILEGIA VULGARIS	A, H	
642	ARACHIDONIC ACID	E	Only for use in topical medicines for dermal application.
643	ARACHIDYL ALCOHOL	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
644	ARACHIDYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 0.5%.
645	ARACHIDYL PROPIONATE	E	Only for use in topical medicines for dermal application.
646	ARACHIS HYPOGAEA	A, E, H	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
647	ARACHIS OIL	A, E, H	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
648	ARALIA CORDATA	A, H	
649	ARALIA HISPIDA	A, H	
650	ARALIA NUDICAULIS	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
651	ARALIA RACEMOSA	A, H	
652	ARCTIUM LAPPA	A, E, H	
653	ARCTIUM MINUS	A, H	
654	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 medicine must be no more than 0.74 %.
655	ARDISIA JAPONICA	A, H	
656	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%.
657	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.
658	ARGININE	A, E, H	Only for use in topical medicines for dermal application. The medicine requires the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.'
659	ARGININE FERULATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
660	ARISAEMA ATRORUBENS	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
661	ARISAEMA CONSANGUINEUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
662	ARISAEMA JAPONICUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
663	ARMORACIA RUSTICANA	A, E, H	Volatile oil components (of Armoracia rusticana) is a mandatory component of Armoracia rusticana. The maximum recommended daily dose must contain no

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			more than 20 mg of volatile oil components (of Armoracia rusticana).
664	ARNEBIA EUCHROMA	A, H	
665	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 Arnica montana.
666	ARNICA MOLLIS	A, H	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
667	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.
668	ARRHENATHERUM ELATIUS	A, H	
669	ARROWROOT	A, E, H	
670	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%.
671	ARSENIC TRIOXIDE	H	Only for use as an active homoeopathic ingredient.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration of arsenic in the medicine must be no more than 0.001%.
672	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%.
673	ARTEMISIA ABSINTHIUM	A, H	Thujone is a mandatory component of Artemisia absinthium. The concentration of thujone from Artemisia absinthium in the medicine must be no more than 4%.
674	ARTEMISIA ANNUA	A, H	Thujone is a mandatory component of Artemisia annua. The concentration of thujone from Artemisia annua in the medicine must be no more than 4%.
675	ARTEMISIA ARBORESCENS	A, H	Thujone is a mandatory component of Artemisia arborescens. The concentration of thujone from Artemisia arborescens in the medicine must be no more than 4%.
676	ARTEMISIA ARGYI	A, H	Thujone is a mandatory component of Artemisia argyi.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration of thujone from Artemisia argyi in the medicine must be no more than 4%.
677	ARTEMISIA DRACUNCULUS	A, E, H	Thujone is a mandatory component of Artemisia dracunculus. The concentration of thujone from Artemisia dracunculus in the medicine must be no more than 4%.
678	ARTEMISIA FRIGIDA	A, H	Thujone is a mandatory component of Artemisia frigida. The concentration of thujone from Artemisia frigida in the medicine must be no more than 4%.
679	ARTEMISIA HERBA-ALBA	A, H	Thujone is a mandatory component of Artemisia herba-alba. The concentration of thujone from Artemisia herba-alba in the medicine must be no more than 4%.
680	ARTEMISIA MARITIMA	A, H	Thujone is a mandatory component of Artemisia maritima. The concentration of thujone from Artemisia maritima in the medicine must be no more than 4%.
681	ARTEMISIA OIL	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 or a fragrance. If used in a flavour 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%.
682	ARTEMISIA PALLENS	A, E, H	Thujone is a mandatory component of Artemisia pallens. The concentration of thujone from Artemisia pallens in the medicine must be no more than 4%.
683	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%.
684	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%.
685	ARTERY	H	Only for use as an active

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			homoeopathic ingredient.
686	ARTHROSPIRA MAXIMA	A, E, H	
687	ARTHROSPIRA PLATENSIS	A, E, H	
688	ARUM MACULATUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
689	ASAFOETIDA GUM	A, H	
690	ASAFOETIDA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
691	ASARUM EUROPAEUM	A, H	
692	ASARUM HETEROTROPOIDES	A, H	
693	ASARUM OIL	E	
694	ASARUM SIEBOLDII	A, E, H	
695	ASCLEPIAS TUBEROSA	A, H	
696	ASCOPHYLLUM NODOSUM	A, E, H	Iodine is a mandatory component of Ascophyllum nodosum. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			maximum recommended daily dose.
697	ASCORBIC ACID	A, E	
698	ASCORBYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
699	ASCORBYL METHYLSILANOL PECTINATE	E	Only for use in topical medicines for dermal application.
700	ASCORBYL PALMITATE	A, E	When for oral use, the maximum recommended daily dose must contain no more than 100mg of ascorbyl palmitate.
701	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%.
702	ASPALATHUS LINEARIS	A, E, H	
703	ASPARAGINE	A, E	

Permissible ingredients and requirements

Column 1	Column 2	Column 3	Column 4
Item	**Ingredient name**	**Purpose**	**Specific requirements**
704	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%.
705	ASPARAGUS	E, H	Only for use as an active homoeopathic or excipient ingredient.
706	ASPARAGUS COCHINCHINENSIS	A, H	
707	ASPARAGUS OFFICINALIS	A, E, H	
708	ASPARAGUS RACEMOSUS	A, H	The plant part must be dried, peeled root, and water extracts or ethanol/water extracts (containing up to 45% ethanol) of the dried, peeled root.
709	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'
710	ASPARTIC ACID	A, E	

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**
711	ASPERGILLUS ORYZAE	A, E, H	
712	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).
713	ASTER NOVI-BELGII	A, H	
714	ASTER TATARICUS	A, H	
715	ASTRAGALUS ADSURGENS	A, H	
716	ASTRAGALUS COMPLANATUS	A, H	
717	ASTRAGALUS EXCARPUS	A, H	
718	ASTRAGALUS GUMMIFER	A, E, H	
719	ASTRAGALUS LENTIGINOSUS	A, H	
720	ASTRAGALUS MEMBRANACEUS	A, E, H	
721	ASTRAGALUS PENDULIFLORUS	A, H	
722	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%.
723	ATRACTYLODES JAPONICA	A, H	
724	ATRACTYLODES LANCEA	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
725	ATRACTYLODES MACROCEPHALA	A, H	
726	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%.
727	ATROPINE SULFATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
728	ATTALEA SPECIOSA	E	Only for use in topical medicines for dermal application.
729	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%.
730	AUREOBASIDIUM PULLULANS	A, H	
731	AVENA FATUA	A, H	Gluten is a mandatory component of Avena fatua when the plant part is seed and

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**
			the route of administration is other than topical and mucosal.
732	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.
733	AVOCADO	E	
734	AVOCADO OIL	E	
735	AVOCADO OIL UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
736	AZADIRACHTA INDICA	A, H	The ingredient can only be derived from the plant part seed and must be cold pressed or debitterised oil. "Debitterised neem seed oil" means highly purified oil from the neem seed containing only fatty acids and glycerides of fatty acids. Cold pressed Azadirachta indica seed oil must be for topical use for dermal application only. When the concentration of cold pressed Azadirachta indica seed oil is more than 1%, a child resistant closure must be fitted to the container. The medicine requires the following warning statements on the medicine label:

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (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).'
737	AZOVAN BLUE	E	Permitted for use only as a colour for topical use.
738	AZULENE	E	Only for use in topical medicines for dermal application.