

Therapeutic Goods (Permissible Ingredients) Determination No. 1of 2018

made under subsection 26BB(1) of the

Therapeutic Goods Act 1989

- I, Mayada Kayali a delegate of the Minister for Health for the purposes of subsection 26BB(1) of the *Therapeutic Goods Act 1989* (the Act), **HEREBY**:
 - (a) Repeal the Therapeutic Goods (Permissible Ingredients) Determination No. 5 of 2017; and
 - (b) Make the following determination specifying:
 - (i) ingredients for the purposes of paragraph 26BB(1)(a) of the Act; and
 - (ii) requirements applying to those ingredients for the purposes of paragraph 26BB(1)(b) of the Act.

Dated this 13th March 2018

(Signed by)

Mayada Kayali

Delegate of the Minister for Health

1 Name of Determination

This Determination is the *Therapeutic Goods (Permissible Ingredients)* Determination No. 1 of 2018.

2 Commencement

This Determination commences on the day after registration of the instrument on the Federal Register of Legislation.

3 Interpretation

In this Determination:

Act means the Therapeutic Goods Act 1989.

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

European Pharmacopoeia is as defined under the Act.

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

4 Permissible ingredients and requirements applying to those ingredients

Permissible ingredients and requirements applying to those ingredients under Table 1

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

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

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

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

Note: Examples of these acronyms are: (CHILD3), (PREGNT), (GLUTEN), (PEANUT) and (ARGIN1).

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

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

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

(section 4)

Part 1—Interpretation of Table 1

Definitions

At Table 1:

"A" means an active ingredient.

Act means the Therapeutic Goods Act 1989.

Active ingredient is as defined in the Regulations.

British Pharmacopoeia is as defined under the Act.

"E" means an excipient.

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

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

"H" means a homoeopathic preparation ingredient.

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

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

Mother tincture is as defined in the Regulations.

Regulations means the Therapeutic Goods Regulations 1990.

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

Table 1 Part 2

Volume 1

Part 2 – Table 1

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 1 | (1,7,7- TRIMETHYLBICYCLO(2.2.1)HEP T-2-YL)-CYCLOHEXANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2 | (1R,2S,5R)-N-(4- METHOXYPHENYL)-5-METHYL- 2-(1-METHYLETHYL) CYCLOHEXANECARBOXAMIDE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%. |
| 3 | (5E)-3-METHYL-5- CYCLOTETRADECEN-1-ONE | E | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 4 | (5Z)-3-METHYL-5- CYCLOTETRADECEN-1-ONE | Е | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 5 | (E)-2-(3,5-DIMETHYLHEX-3-EN- 2-YLOXY)-2-METHYLPROPYL CYCLOPROPANECARBOXYLAT E | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 6 | (E)-3- METHYLCYCLOPENTADEC-5- EN-1-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 7 | (E, E)-2,6-NONADIENAL | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour concentration in a medicine must be no more than 5%. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 8 | (S)- LACTIC ACID | A, E, H | |
| 9 | (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 antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 10 | (S)-S-ADENOSYLMETHIONINE DISULFATE TOSYLATE | A | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tosylate. |
| | | | (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | requires the following warning statement on the medicine label: |
| | | | - (SAME) 'Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 11 | (S)-S-ADENOSYLMETHIONINE DISULFATE TRITOSYLATE DIHYDRATE | A | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tritosylate dihydrate. (S)-S-Adenosylmethionine in 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 antidepressants 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 HEXASULFATE DIHYDRATE | A | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine hexasulfate dihydrate. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | (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 antidepressants 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 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)' |
| | | | |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 14 | (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 antidepressants 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 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 antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | effect)' |
| 16 | (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 antidepressants 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 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 antidepressants or suffer from bipolar depression should not |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 18 | (S)-S-ADENOSYLMETHIONINE TRISULFATE DITOSYLATE DIHYDRATE | A | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine trisulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 19 | (Z)-HEX-3-ENYL 2- ETHYLBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 20 | (Z, Z)-3,6-NONADIEN-1-OL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 21 | (±)-NARINGENIN | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 22 | 1,1,1-TRICHLOROETHANE | E | The concentration in the medicine must be no more than 25%. |
| 23 | 1,2-HEXANEDIOL | E | Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye. The concentration in the medicine must be no more than |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 1%. |
| 24 | 1,3,4,6,7,8A-HEXAHYDRO-1,1,5,5- TETRAMETHYL-2H-2,4A- METHANONAPHTHALEN-8(5H)- ONE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 25 | 1,3,5-UNDECATRIENE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 26 | 1,3-BUTYLENE GLYCOL | Е | |
| 27 | 1,3-NONANEDIOL ACETATE, MIXED ESTERS | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 28 | 1,3-NONANEDIOL, DIACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 29 | 1,4-CINEOLE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1% |
| 30 | 1,4- DIOXACYCLOHEXADECANE- 5,16-DIONE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 1%. |
| 31 | 1,5,9-TRIMETHYL-13- OXABICYCLO[10.1.0]TRIDECA- 4,8-DIENE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 32 | 1,7,7- TRIMETHYLBICYCLO[4.4.0]DEC AN-3-YL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 33 | 1-(2,2,6- TRIMETHYLCYCLOHEXYL)-3- HEXANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 34 | 1-(2,6,6-TRIMETHYL-2- CYCLOHEXEN-1-YL)-1-PENTEN- | E | Permitted for use only in combination with other |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | 3-ONE | | permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 35 | 1-(3,3- DIMETHYLCYCLOHEXYL)ETHY L FORMATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 36 | 1-(4- ISOPROPYLCYCLOHEXYL)ETH ANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 37 | 1-(5,5-DIMETHYL-1- CYCLOHEXEN-1-YL)-4-PENTEN- 1-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 1%. |
| 38 | 1-DODECANOL | E | Permitted for use: (a) only in combination with other permitted ingredients as a flavour; and (b) in topical medicines for dermal application. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 39 | 1-HEPTANOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 40 | 1-HEXEN-3-OL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 1%. |
| 41 | 1-METHOXY-4- PROPENYLBENZENE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 42 | 1-METHYL-2-[(1,2,2- TRIMETHYLBICYCLO[3.1.0]HEX -3-YL)METHYL]- CYCLOPROPANEMETHANOL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 43 | 1-METHYL-3-(2- METHYLPROPYL)- CYCLOHEXANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 44 | 1-METHYL-4-(4-METHYL-3- PENTENYL)-3-CYCLOHEXENE- | Е | Permitted for use only in combination with other permitted ingredients as a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | 1-CARBOXALDEHYDE | | fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 45 | 1-OCTEN-3-ONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 46 | 1-P-MENTHENE-8-THIOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 47 | 1-PENTEN-3-OL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 48 | 10-UNDECEN-1-OL | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 49 | 10-UNDECENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 50 | 16-HYDROXY-12- OXAHEXADECANOIC ACID, OMEGA-LACTONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 51 | 2,2,3-TRIMETHYLCYCLOPENT- 3-ENE-1-ETHYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 52 | 2,2,5-TRIMETHYL-5- PENTYLCYCLOPENTANONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 53 | 2,2-DIMETHYL-3-(3-METHYL-2,4-PENTADIENYL)-OXIRANE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 54 | 2,2-DIMETHYL-3- PHENYLPROPANOLL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 55 | 2,2-DIMETHYL-5-(1- METHYLPROPEN-1-YL) TETRAHYDROFURAN | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 56 | 2,2-DIMETHYL-P- ETHYLPHENYL- PROPANENITRILE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 57 | 2,3,4-TRIMETHYL-3-PENTANOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 58 | 2,3,5,6- TETRAMETHYLPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 59 | 2,3,5-TRIMETHYLPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 60 | 2,3-DIETHYLPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 61 | 2,3-DIHYDRO-2,5-DIMETHYL- 1H-INDENE-2-METHANOL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 1%. |
| 62 | 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%. |
| 63 | 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%. |
| 64 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 65 | 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%. |
| 66 | 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%. |
| 67 | 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%. |
| 68 | 2,4-DECADIENAL | Е | Permitted for use only in combination with other permitted ingredients as a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour or a fragrance. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| | | | If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. |
| | | | The maximum daily dose must provide no more than 3 mg of 2,4-Decadienal. |
| | | | |
| 69 | 2,4-DIMETHYL BUTADIENEACROLEIN | Е | Permitted for use only in combination with 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-DIMETHYL THIAZOLE | E | Permitted for use only in combination with other permitted ingredients as a flavour. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 71 | 2,4-DIMETHYL-3- | E | Permitted for use only in |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | CYCLOHEXENE CARBOXALDEHYDE | | combination with 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-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%. |
| 73 | 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%. |
| 74 | 2,4-HEPTADIENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 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. |
| 75 | 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. |
| 76 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 5%. |
| 77 | 2,5-DIMETHYL-2-OCTEN-6-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 78 | 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%. |
| 79 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 80 | 2,5-DIMETHYLPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance, or a printing ink. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1% |
| 81 | 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%. |
| 82 | 2,6,9,10-TETRAMETHYL-1- | E | Permitted for use only in |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | OXASPIRO(4.5)DECA-3,6-DIENE | | combination with other permitted ingredients as a fragrance. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 83 | 2,6-DIMETHOXYPHENOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 84 | 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%. |
| 85 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 86 | 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%. |
| 87 | 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%. |
| 88 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance concentration in a medicine must be no more 1%. |
| 89 | 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%. |
| 90 | 2,6-OCTADIENOIC ACID, 3,7-DIMETHYL-, METHYL ESTER, (2E)- | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 91 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 92 | 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%. |
| 93 | 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%. |
| 94 | 2-[(3,7-DIMETHYL-6-OCTEN-1-YLIDENE)AMINO]BENZOIC ACID, METHYL ESTER | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 95 | 2-[1-(3,3- DIMETHYLCYCLOHEXYL)ETHO XY]-2-METHYLPROPYL] CYCLOPROPANECARBOXYLAT E | Е | Permitted for use only in combination with 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-[1-(3,3- DIMETHYLCYCLOHEXYL)ETHO XY]-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%. |
| 97 | 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%. |
| 98 | 2-ACETYLPYRAZINE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 5%. |
| 99 | 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%. |
| 100 | 2-AMINO-2-METHYL-1- PROPANOL | Е | Only for use in topical medicines for dermal application. |
| 101 | 2-BENZYL-4,4,6-TRIMETHYL-1,3-DIOXANE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 102 | 2-BUTEN-1-OL | Е | Permitted for use only in combination with other permitted ingredients as a |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 103 | 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%. |
| 104 | 2-CYCLOHEXYLIDENE-2-O- TOLYL-ACETONITRILE | Е | Permitted for use only in combination with 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-DECENAL | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 5%. |
| 106 | 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 1%. |
| 107 | 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%. |
| 108 | 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 |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 1%. |
| 109 | 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%. |
| 110 | 2-ETHYL-1-HEXANOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 111 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 112 | 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%. |
| 113 | 2-ETHYL-3-METHYLPYRAZINE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 114 | 2-ETHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-2-BUTEN-1-OL | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 115 | 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%. |
| 116 | 2-ETHYL-4-METHYLTHIAZOLE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 117 | 2-ETHYL-ALPHA,ALPHA- DIMETHYL- BENZENEPROPANAL | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 118 | 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%. |
| 119 | 2-HEPTANOL | Е | Permitted for use only in combination with 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-HEPTANONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 121 | 2-HEPTYL CYCLOPENTANONE | Е | Permitted for use only in combination with other permitted ingredients as a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 122 | 2-HEXENYL ACETATE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 123 | 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%. |
| 124 | 2-ISOBUTYL-3- METHOXYPYRAZINE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 125 | 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%. |
| 126 | 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%. |
| 127 | 2-ISOPROPYL-4- METHYLTHIAZOLE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| | | | If used in a fragrance the total fragrance concentration in a |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more 1%. |
| 128 | 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%. |
| 129 | 2-METHOXY-3- SECBUTYLPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 130 | 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%. |
| 131 | 2-METHYL BUTYRIC ACID | Е | Permitted for use only in combination with other permitted ingredients as a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour or a fragrance. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 132 | 2-METHYL HEPTANOIC ACID | Е | Permitted for use only in combination with 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-METHYL-2-PENTENOIC ACID | Е | Permitted for use only in combination with other permitted ingredients as a flavour. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 134 | 2-METHYL-2-VINYL-5- ISOPROPENYLTETRAHYDROFU RAN | Е | Permitted for use only in combination with other permitted ingredients as a flavour. |
| | | | If used in a flavour the total |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour concentration in a medicine must be no more than 5%. |
| 135 | 2-METHYL-3-(3,4- METHYLENEDIOXYPHENYL)PR OPANAL | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 136 | 2-METHYL-3-(4- METHOXYPHENYL)PROPANAL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 137 | 2-METHYL-3-[4-(2- METHYLPROPYL)PHENYL]PROP ANAL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 1%. |
| 138 | 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%. |
| 139 | 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%. |
| 140 | 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%. |
| 141 | 2-METHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTENYL)-2-BUTEN- | Е | Permitted for use only in combination with other permitted ingredients as a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | 1-OL | | 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. |
| 142 | 2-METHYL-4-(2,6,6-TRIMETHYL- 1-CYCLOHEXEN-1-YL)-2- BUTENAL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 143 | 2-METHYL-4-(CAMPHENYL-8)- CYCLOHEXANONE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 144 | 2-METHYL-4-PROPYL-1,3- OXTHIANE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 145 | 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%. |
| 146 | 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%. |
| 147 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 148 | 2-METHYLBUTYL ISOVALERATE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 149 | 2-METHYLBUTYL PHENYLETHYL ETHER | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 150 | 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%. |
| 151 | 2-METHYLHEXANOIC ACID | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 5%. |
| 152 | 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%. |
| 153 | 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%. |
| 154 | 2-METHYLUNDECANAL | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 155 | 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%. |
| 156 | 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%. |
| 157 | 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 |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 1%. |
| 158 | 2-OXOBUTYRIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 159 | 2-PENTADECANONE | Е | 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%. |
| 160 | 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%. |
| 161 | 2-PENTANONE | Е | Permitted for use only in combination with other |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 162 | 2-PENTENAL | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 163 | 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%. |
| 164 | 2-PHENYLPROPIONALDEHYDE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a |
| | | | medicine must be no more 1%. |
| 165 | 2-PHENYLPROPIONALDEHYDE DIMETHYL ACETAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| | | | |
| 166 | 2-PROPENOIC ACID | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 167 | 2-SEC-BUTYL CYCLOHEXANONE | Е | Permitted for use only in combination with other permitted ingredients as a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 168 | 2-TERT- BUTYLCYCLOHEXANOL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 169 | 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%. |
| 170 | 2-TRANS-6-CIS-NONADIENAL | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 171 | 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%. |
| 172 | 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%. |
| 173 | 2-TRIDECENENITRILE | E | Permitted for use only in combination with other permitted ingredients as a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 174 | 2-UNDECENAL | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 175 | 3,3-DIMETHYL-5-(2,2,3- TRIMETHYL-3-CYCLOPENTEN- 1-YL)-4-PENTEN-2-OL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 176 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 177 | 3,4,4A,5,8,8A-HEXAHYDRO-3',7- DIMETHYLSPIRO-1,4- METHANONAPHALENE-2(1H),2'- OXIRANE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 178 | 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%. |
| 179 | 3,5,5-TRIMETHYL HEXANAL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 180 | 3,5,5-TRIMETHYLHEXYL ACETATE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 181 | 3,5,6,6-TETRAMETHYL-4- METHYLENEHEPTAN-2-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 182 | 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%. |
| 183 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 184 | 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%. |
| 185 | 3,7-DIMETHYL OCTANAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 186 | 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%. |
| 187 | 3,7-DIMETHYL-2,6- NONADIENENITRILE | E | Permitted for use only in combination with other permitted ingredients as a |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 188 | 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%. |
| 189 | 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%. |
| 190 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 191 | 3-(4-HYDROXYPHENYL)-1-(2,4,6- TRIHYDROXYPHENYL)-1- PROPANONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 192 | 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%. |
| 193 | 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%. |
| 194 | 3-(METHYLTHIO)-1-HEXYL ACETATE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 195 | 3-CARENE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 196 | 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%. |
| 197 | 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 |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 5%. |
| 198 | 3-HEPTYLDIHYDRO-5-METHYL- 2(3H)-FURANONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 199 | 3-HEXANONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 200 | 3-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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 201 | 3-ISO-CAMPHYL-5- CYCLOHEXAN-1-OL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 202 | 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%. |
| 203 | 3-METHYL-2- (PENTYLOXY)CYCLOPENT-2- EN-1-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 204 | 3-METHYL-5-(2,2,3-TRIMETHYL- 3-CYCLOPENTEN-1-YL)-4- PENTEN-2-OL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 1%. |
| 205 | 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%. |
| 206 | 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%. |
| 207 | 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%. |
| 208 | 3-METHYL-5- | Е | Permitted for use only in combination with other |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | PHENYLPENTANOL | | permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 209 | 3-METHYL-5-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%. |
| 210 | 3- METHYLCYCLOPENTADECANO NE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 211 | 3- METHYLCYCLOPENTADECENO NE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 1%. |
| 212 | 3-METHYLTHIOHEXANOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 213 | 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%. |
| 214 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 215 | 3-PENTYLTETRAHYDRO-2H- | E | Permitted for use only in |
| 213 | PYRAN-4-OL ACETATE | E | combination with 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-PHENYLPROPIONALDEHYDE | E | Permitted for use only in |
| 210 | 3 THENTE ROTTON REDETITIES | | combination with other permitted ingredients as a flavour or a fragrance. |
| | | | If used in a flavour the total flavour concentration in 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%. |
| 217 | 3-PHENYLPROPYL ACETATE | E | Permitted for use only in |
| 217 | 5-FHENTLFROFTL ACETATE | E | combination with other permitted ingredients as a flavour or a fragrance. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| | | | If used in a fragrance the total fragrance concentration in a |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more 1%. |
| 218 | 3-PHENYLPROPYL PROPIONATE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 219 | 3-PROPYLIDENE PHTHALIDE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 220 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 221 | 3A,6,6,9A- TETRAMETHYLDODECAHYDRO NAPHTHO[2,1-B] FURAN | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 222 | 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%. |
| 223 | 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%. |
| 224 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 5%. |
| 225 | 4,7-METHANO-1H-INDENEMETHANOL, OCTAHYDRO-, ACETATE | Е | 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%. |
| 226 | 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%. |
| 227 | 4,8-DIMETHYL-3,7-NONADIEN- 2-OL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 228 | 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%. |
| 229 | 4-(4-METHYL-3-PENTEN-1-YL)- 3-CYCLOHEXENE-1- CARBOXALDEHYDE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 230 | 4-(5,5,6- TRIMETHYLBICYCLO(2.2.1)HEP T-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%. |
| 231 | 4-(METHYLTHIO)-4-METHYL-2- PENTANONE | Е | Permitted for use only in combination with other permitted ingredients as a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 232 | 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%. |
| 233 | 4-(PARA-METHOXYPHENYL)-2-BUTANONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 234 | 4-ACETYL-6-TERTIARY-BUTYL- 1,1-DIMETHYLINDAN | E | Permitted for use only in combination with other |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 235 | 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%. |
| 236 | 4-HEPTANONE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 237 | 4-HYDROXYBENZALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 238 | 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%. |
| 239 | 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%. |
| 240 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 241 | 4-METHYL-4- MERCAPTOPENTAN-2-ONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 242 | 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%. |
| 243 | 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%. |
| 244 | 4-METHYLBENZYLIDENE CAMPHOR | A | Only for use as an active ingredient in sunscreens for dermal application and not to |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | be included in medicines intended for use in the eye. |
| | | | The concentration in the medicine must be no more than 4%. |
| | | | When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: |
| | | | - (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). |
| | | | When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: |
| | | | - (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). |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 245 | 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%. |
| 246 | 4-METHYLPHENYL OCTANOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 247 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 248 | 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%. |
| 249 | 4-TERT-BUTYL-2,6-DIMETHYL ACETOPHENONE | Е | Permitted for use only in combination with 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-TERT- BUTYLCYCLOHEXANOL | Е | 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%. |
| 251 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 1%. |
| 252 | 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%. |
| 253 | 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%. |
| 254 | 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%. |
| 255 | 5-ACETYL-1,1,2,3,3,6- | Е | Permitted for use only in combination with other |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | HEXAMETHYL INDAN | | permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 256 | 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%. |
| 257 | 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%. |
| 258 | 5-ETHYL-4-HYDROXY-2- METHYL-3(2H)-FURANONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 259 | 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%. |
| 260 | 5-METHOXYPSORALEN | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total |
| 261 | 5-METHYL 2-PHENYL HEXEN-2- | E | fragrance concentration in a medicine must be no more than 1%. Permitted for use only in combination with other |
| | AL | | permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 262 | 5-METHYL-2-THIOPHENE CARBOXALDEHYDE | Е | Permitted for use only in combination with 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-METHYL-3- BUTYLTETRAHYDROPYRAN-4- YL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 264 | 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%. |
| 265 | 5-PENTYL-2(5H)-FURANONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 5%. |
| 266 | 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%. |
| 267 | 6,6-DIMETHYL-2- NORPINENEPROPIONALDEHYD E | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 268 | 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%. |
| 269 | 6-BUTYL-3,6-DIHYDRO-2,4- | Е | Permitted for use only in combination with other |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | DIMETHYL-2H-PYRAN | | permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 270 | 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%. |
| 271 | 6- METHOXYDICYCLOPENTADIEN ECARBOXALDEHYDE | Е | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. When included in a medicine for use on the lips the concentration of 6-methoxydicyclopentadiene carboxaldehyde must be no more than 0.1%. When included in dermal creams for infant use the concentration of 6-methoxydicyclopentadienecarb oxaldehyde must be no more |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | than 0.5%. When for dermal use or use on the hair the concentration of 6-methoxydicyclopentadienecarb oxaldehyde must be no more than 0.5%. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 272 | 6-METHYL COUMARIN | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 273 | 6-METHYL-2-BUTEN-3-OL-2 | Е | |
| 274 | 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%. |
| 275 | 7-METHYL-2H-1,5- | Е | Permitted for use only in combination with other |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | BENZODIOXEPIN-3(4H)-ONE | | permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 276 | 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%. |
| 277 | 7-PROPYL-2H-1,5- BENZODIOXEPIN-3(4H)-ONE | Е | Permitted for use only in combination with 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 | 8,13:13,20-DIEPOXY-14,15- BISNORLABDANE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 279 | 8-METHYL-1- OXASPIRO(4,5)DECAN-2-ONE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total |
| | | | fragrance concentration in a medicine must be no more than 1%. |
| 280 | 8-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%. |
| 281 | 9-DECEN-1-OL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 282 | ABELMOSCHUS MOSCHATUS | A, H | |
| 283 | ABELMOSCHUS MOSCHATUS SUBSP. MOSCHATUS | А, Н | |
| 284 | ABIES BALSAMEA | A, H | |
| 285 | ABIES NIGRA | A, H | |
| 286 | ABIES PECTINATA | A, H | |
| 287 | ABIES SIBIRICA | A, H | |
| 288 | 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. |
| 289 | ABUTILON THEOPHRASTI | A, H | |
| 290 | ACACIA | A, E, H | |
| 291 | ACACIA BAILEYANA | A, H | |
| 292 | ACACIA CATECHU | A, H | |
| 293 | ACACIA DEALBATA | A, H | |
| 294 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 295 | 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%. |
| 296 | ACACIA LONGIFOLIA | A, E, H | |
| 297 | ACACIA NILOTICA | A, E, H | |
| 298 | ACACIA SENEGAL | A, E, H | |
| 299 | ACALYPHA INDICA | A, H | |
| 300 | ACANTHUS MOLLIS | A, H | |
| 301 | ACER CAMPESTRE | A, H | |
| 302 | ACER NEGUNDO | A, H | |
| 303 | ACER SACCHARINUM | A, H | |
| 304 | ACER SACCHARUM | A, E, H | |
| 305 | ACEROLA | Е | |
| 306 | ACESULFAME POTASSIUM | Е | |
| 307 | 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%. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 308 | 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%. |
| 309 | ACETALDEHYDE ETHYL LINALYL ACETAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 310 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 1%. |
| 311 | 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%. |
| 312 | 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%. |
| 313 | ACETIC ACID | E, H | The concentration in the medicine must be no more than 80%. |
| 314 | ACETOIN | Е | Permitted for use only in combination with other |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 315 | ACETOMENAPHTHONE | A, E | |
| 316 | 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%. |
| 317 | ACETOPHENONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 318 | ACETOVANILLONE | Е | Only for use in topical medicines for dermal application. Permitted for use only in |
| | | | combination with other permitted ingredients as a fragrance. |
| | | | If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 319 | 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%. |
| 320 | 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%. |
| 321 | ACETYL GLUCOSAMINE | Е | Only for use in topical medicines for dermal application and not to be |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%. If the ingredient is sourced from seafood, then the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood' |
| 322 | ACETYL HEXAMETHYL TETRALIN | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 323 | ACETYL LEVOCARNITINE HYDROCHLORIDE | A, E | |
| 324 | ACETYL TRIFLUOROMETHYLPHENYL VALYLGLYCINE | Е | 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%. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 325 | ACETYLATED LANOLIN | Е | Only for use in topical medicines for dermal application. |
| 326 | ACETYLATED LANOLIN ALCOHOL | E | Only for use in topical medicines for dermal application. |
| 327 | ACETYLATED MONOGLYCERIDES | Е | |
| 328 | 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%. |
| 329 | ACETYLCYSTEINE | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.001%. |
| 330 | ACHILLEA ERBA-ROTTA SUBSP. MOSCHATA | A, H | |
| 331 | ACHILLEA MILLEFOLIUM | A, E, H | |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 332 | ACHILLEA PTARMICA | A, H | |
| 333 | ACHYRANTHES ASPERA | A, H | |
| 334 | ACHYRANTHES BIDENTATA | A, H | |
| 335 | ACHYRANTHES FAURIEI | A, H | |
| 336 | ACID GREEN 25 | Е | Permitted for use only as a colour for topical use. |
| 337 | ACID RED 33 | E | Permitted for use only as a colour for topical use. |
| 338 | ACID RED 87 | E, H | Only for use as an active homoeopathic ingredient or for excipient use as a colour in topical medicines. |
| 339 | ACID TREATED WAXY MAIZE STARCH | E | |
| 340 | 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%. |
| 341 | ACONITUM CARMICHAELII | A, H | Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | carmichaelii. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack. |
| 342 | 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. |
| 343 | 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. |
| 344 | 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. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 345 | ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURAT E 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%. |
| 346 | ACRYLAMIDES COPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 347 | ACRYLATES COPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 348 | ACRYLATES/ACRYLAMIDE COPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 349 | ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 350 | ACRYLATES/C12-22 ALKYL METHACRYLATE COPOLYMER | Е | 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 |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 5%. |
| 351 | 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%. |
| 352 | ACRYLATES/OCTYLACRYLAMI DE COPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 353 | 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%. |
| 354 | ACRYLATES/VA COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 355 | ACRYLIC ACID/VP CROSSPOLYMER | Е | Only for use in topical medicines for dermal |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | application and not to be included in medicines intended for use in the eye. |
| | | | The concentration in the medicine must be no more than 2.5%. |
| 356 | ACTAEA CIMICIFUGA | A, H | |
| 357 | ACTAEA HERACLEIFOLIA | A, H | |
| 358 | ACTAEA PACHYPODA | A, H | |
| 359 | ACTAEA RACEMOSA | A, H | When used in oral medicines, the medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.' |
| 360 | ACTAEA SIMPLEX | A, H | |
| 361 | ACTAEA SPICATA | A, H | |
| 362 | ACTINIDIA CHINENSIS | A, H | |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 363 | ACTINIDIA DELICIOSA | A, H | |
| 364 | 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. |
| 365 | 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). |
| 366 | ADEMETIONINE DISULFATE DITOSYLATE DIHYDRATE | A, H | (S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate ditosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | statement on the medicine label: - (SAME) 'Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that |
| 367 | ADEMETIONINE DISULFATE TOSYLATE | A, H | effect)' (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 antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 368 | ADEMETIONINE DISULFATE TRITOSYLATE DIHYDRATE | A, H | (S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tritosylate dihydrate. Ademetionine in the form of |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: |
| | | | - (SAME) 'Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 369 | ADEMETIONINE HEXASULFATE DIHYDRATE | А, Н | (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 antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 370 | ADEMETIONINE HEXATOSYLATE DIHYDRATE | А, Н | (S)-S-Adenosylmethionine is a mandatory component of |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | Ademetionine hexatosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 371 | 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 antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 372 | 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 label: - (SAME) 'Individuals who are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 373 | ADEMETIONINE 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 antidepressants or suffer from bipolar depression should not use this product unless under |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | the supervision of a healthcare practitioner (or words to that effect)' |
| 374 | 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 are using prescription antidepressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 375 | 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- |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 376 | ADENOPHORA STRICTA | A, H | |
| 377 | ADENOPHORA TRIPHYLLA | A, H | |
| 378 | 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%. |
| 379 | 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%. |
| 380 | ADENOSINE TRIPHOSPHATE | E | Only for use in topical medicines for dermal application. |

Table 1 Part 2

| ingredient in the medicine applying to the ingredient in Column 2 ADENOSINE TRIPHOSPHATE DISODIUM BE Only for use in topical medicines for dermal application. ADIPIC ACID BE Only for use in topical medicines for dermal application. E Only for use in topical medicines for dermal application and not to be included in medicines intent for use in the eye. The concentration in the medicine must be no more 5%. ADONIS VERNALIS A, H The concentration of equivalent dry Adonis vern in the medicine must be no | Column 1 | Column 2 | Column 3 | Column 4 |
|--|----------|---------------------------|---------------|---|
| DISODIUM medicines for dermal application. 382 ADIANTUM CAPILLUS-VENERIS A, H 383 ADIPIC ACID E 384 ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER Donly for use in topical medicines for dermal application and not to be included in medicines inter for use in the eye. The concentration in the medicine must be no more 5%. 385 ADONIS VERNALIS A, H The concentration of equivalent dry Adonis vern in the medicine must be no more than 10mg/Kg or 10m or 0.001%. | | Ingredient Name | ingredient in | Specific requirements(s) applying to the ingredient in Column 2 |
| DISODIUM medicines for dermal application. 382 ADIANTUM CAPILLUS-VENERIS A, H 383 ADIPIC ACID E 384 ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER Donly for use in topical medicines for dermal application and not to be included in medicines inter for use in the eye. The concentration in the medicine must be no more 5%. 385 ADONIS VERNALIS A, H The concentration of equivalent dry Adonis vern in the medicine must be no more than 10mg/Kg or 10m or 0.001%. | | | | |
| 383 ADIPIC ACID 384 ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER BE Only for use in topical medicines for dermal application and not to be included in medicines intent for use in the eye. The concentration in the medicine must be no more 5%. 385 ADONIS VERNALIS A, H The concentration of equivalent dry Adonis vern in the medicine must be no more than 10mg/Kg or 10m or 0.001%. 386 ADRENALINE (EPINEPHRINE) H Only for use as an active | 381 | | Е | medicines for dermal |
| ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER E Only for use in topical medicines for dermal application and not to be included in medicines intent for use in the eye. The concentration in the medicine must be no more 5%. A, H The concentration of equivalent dry Adonis vern in the medicine must be no more than 10mg/Kg or 10m or 0.001%. ADRENALINE (EPINEPHRINE) H Only for use in topical medicines in topical medicines for dermal application and not to be included in medicines intent for use in the eye. The concentration of equivalent dry Adonis vern in the medicine must be no more than 10mg/Kg or 10m or 0.001%. | 382 | ADIANTUM CAPILLUS-VENERIS | А, Н | |
| GLYCOL/GLYCERIN CROSSPOLYMER medicines for dermal application and not to be included in medicines intent for use in the eye. The concentration in the medicine must be no more 5%. A, H The concentration of equivalent dry Adonis vern in the medicine must be no more than 10mg/Kg or 10m or 0.001%. ADRENALINE (EPINEPHRINE) H Only for use as an active | 383 | ADIPIC ACID | Е | |
| equivalent dry Adonis vern in the medicine must be no more than 10mg/Kg or 10m or 0.001%. 386 ADRENALINE (EPINEPHRINE) H Only for use as an active | 384 | GLYCOL/GLYCERIN | E | 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 |
| | 385 | ADONIS VERNALIS | А, Н | equivalent dry Adonis vernalis in the medicine must be no more than 10mg/Kg or 10mg/L |
| | 386 | ADRENALINE (EPINEPHRINE) | Н | |
| 387 ADZUKI BEAN E | 387 | ADZUKI BEAN | E | |
| 388 AEGOPODIUM PODAGRARIA A, H | 388 | AEGOPODIUM PODAGRARIA | A, H | |
| 389 AESCULUS CHINENSIS A, H | 389 | AESCULUS CHINENSIS | A, H | |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 390 | AESCULUS GLABRA | A, H | |
| 391 | AESCULUS HIPPOCASTANUM | A, H | |
| 392 | AESCULUS X CARNEA | A, H | |
| 393 | AETHUSA CYNAPIUM | Н | Only for use as an active homoeopathic ingredient. |
| 394 | AGAR | A, E | |
| 395 | AGASTACHE RUGOSA | A, H | |
| 396 | 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%. |
| 397 | AGAVE AMERICANA | A, E, H | |
| 398 | AGRIMONIA EUPATORIA | A, E, H | |
| 399 | AGRIMONIA REPENS | A, H | |
| 400 | AGROSTIS TENUIS | A, H | |
| 401 | AILANTHUS ALTISSIMA | A, H | |
| 402 | AJUGA CHAMAEPITYS | A, H | |
| 403 | AJUGA REPTANS | A, H | |
| 404 | ALANINE | A, E | |
| 405 | ALANYLGLUTAMINE | A | Only for use in oral medicines. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 406 | ALARIA ESCULENTA | A, H | Iodine is a mandatory component of Alaria esculenta. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 407 | ALBIZIA JULIBRISSIN | A, H | |
| 408 | ALBIZIA LEBBECK | A, H | |
| 409 | ALCEA ROSEA | A, H | |
| 410 | ALCHEMILLA ALPINA | A, H | |
| 411 | ALCHEMILLA ARVENSIS | A, H | |
| 412 | ALCHEMILLA VULGARIS | A, H | |
| 413 | ALETRIS FARINOSA | A, H | |
| 414 | ALETRIS SPICATA | A, H | |
| 415 | ALEURITES MOLUCCANUS SEED OIL | E | Only for use in topical medicines for dermal application. |
| 416 | ALFADEX | A, E | Only for use in oral medicines. The maximum daily dose must provide no more than 6 g of |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | alfadex. |
| 417 | ALGINATE-KONJAC-XANTHAN POLYSACCHARIDE COMPLEX | A | Only for use in oral medicines. Only for use when the dosage form is other than tablet. The maximum recommended daily dose must be no more than 13.5 g. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' 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). |
| 418 | ALGINIC ACID | E | |
| 419 | ALISMA ORIENTALE | A, H | |
| 420 | ALISMA PLANTAGO AQUATICA | А, Н | |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 421 | ALKANNA TINCTORIA | A, H | |
| 422 | 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%. |
| 423 | ALLANTOIN | E | Only for use in topical medicines for dermal application. |
| 424 | ALLIARIA PETIOLATA | A, H | |
| 425 | ALLIUM CEPA | A, H | |
| 426 | ALLIUM FISTULOSUM | A, H | |
| 427 | ALLIUM HIEROCHUNTINUM | A, H | |
| 428 | ALLIUM MACROSTEMON | A, H | |
| 429 | ALLIUM ODORUM | A, H | |
| 430 | ALLIUM PORRUM | A, H | |
| 431 | ALLIUM SATIVUM | A, E, H | |
| 432 | ALLIUM SCHOENOPRASUM | A, H | |
| 433 | ALLIUM URSINUM | A, H | |
| 434 | ALLO-OCIMENE | E | Permitted for use only in combination with other permitted ingredients as a |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 435 | ALLURA RED AC | E | Permitted for use only as a colour for oral and topical use. |
| 436 | ALLURA RED AC ALUMINIUM LAKE | E | Permitted for use only as a colour for oral and topical use. |
| 437 | ALLYL ALPHA-IONONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 438 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 1%. |
| 439 | 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%. |
| 440 | 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%. |
| 441 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance concentration in a medicine must be no more 1%. |
| 442 | 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%. |
| 443 | 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%. |
| 444 | ALLYL HEXANOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 445 | 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%. |
| 446 | 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%. |
| 447 | ALLYL TIGLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. |
| | | | If used in a flavour the total |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour concentration in a medicine must be no more than 5%. |
| 448 | ALMOND | Е | |
| 449 | 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%. |
| 450 | ALNUS GLUTINOSA | A, H | |
| 451 | ALNUS INCANA SUBSP. RUGOSA | A, H | |
| 452 | 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 |

Table 1 Part 2

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

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 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'. |
| 453 | 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 |

Table 1 Part 2

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

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 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'. |
| 454 | ALOE VERA | A, E, H | When the route of administration is oral or 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'; |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 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 |
| | | | medicine requires the following warning statements |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 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'. |
| 455 | ALOES CAPE | A, H | When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloes cape. |
| | | | When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: |
| | | | - (CHILD3) 'Use in children under 12 years is not recommended'; |
| | | | - (LAX2) 'Prolonged use may cause serious bowel problems'; and |
| | | | - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you |

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

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | recommended'; |
| | | | - (LAX1) 'Drink plenty of water' [or words to that effect]; and |
| | | | - (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 1.5 | | | |
| 456 | ALOYSIA CITRODORA | А, Н | |
| 457 | 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.' |
| 458 | ALPHA LIPOIC ACID | A | |
| 459 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 460 | ALPHA-AMYL CINNAMALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 461 | 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%. |
| 462 | 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%. |
| 463 | ALPHA-DAMASCONE | E | Permitted for use only in combination with other permitted ingredients as a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour or a fragrance. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 464 | 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%. |
| 465 | ALPHA-FURFURYL OCTANOATE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 466 | ALPHA- HEXYLCINNAMALDEHYDE | Е | Permitted for use only in combination with other |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 467 | 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%. |
| 468 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more 1%. |
| 469 | 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%. |
| 470 | 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%. |
| 471 | ALPHA-METHYL ANISALACETONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour concentration in a medicine must be no more than 5%. |
| 472 | 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%. |
| 473 | ALPHA-METHYL BUTYRALDEHYDE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 474 | ALPHA-METHYL 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 |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more 1%. |
| 475 | 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%. |
| 476 | 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%. |
| 477 | ALPHA-METHYL NAPHTHYL KETONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 478 | 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%. |
| 479 | 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%. |
| 480 | 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 fragrance concentration in a medicine must be no more 1%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 481 | ALPHA-PINENE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 482 | 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%. |
| 483 | ALPHA-TERPINENE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance concentration in a medicine must be no more 1%. |
| 484 | 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%. |
| 485 | ALPINIA GALANGA | A, H | |
| 486 | ALPINIA HAINANENSIS | A, H | |
| 487 | ALPINIA OFFICINARUM | A, H | |
| 488 | ALPINIA OXYPHYLLA | A, H | |
| 489 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | dose. |
| 490 | ALSTONIA BOONEI | A, H | |
| 491 | ALSTONIA CONSTRICTA | Н | Only for use as an active homoeopathic ingredient. |
| 492 | ALTERNANTHERA PHILOXEROIDES | A, H | |
| 493 | 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%. |
| 494 | ALTHAEA OFFICINALIS | A, E, H | |
| 495 | ALUM DODECAHYDRATE | A, E, H | |
| 496 | ALUMINIUM CHLOROHYDRATE | E | Only for use in topical medicines for dermal application. |
| 497 | ALUMINIUM CITRATE | E | Only for use in topical medicines for dermal application. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 498 | ALUMINIUM DISTEARATE | Е | Only for use in topical medicines for dermal application. |
| 499 | ALUMINIUM HYDROXIDE | E | Only for use in topical medicines for dermal application. |
| 500 | ALUMINIUM HYDROXIDE HYDRATE | E | Only for use in topical medicines for dermal application. |
| 501 | ALUMINIUM MAGNESIUM SILICATE | Е | |
| 502 | ALUMINIUM MONOSTEARATE | Е | Only for use in topical medicines for dermal application. |
| 503 | 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. |
| 504 | ALUMINIUM SILICATE | E, H | Only for use as an active homoeopathic or excipient ingredient. When used as an excipient ingredient, the medicine is only |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | for use in topical medicines for dermal application. |
| 505 | 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).' |
| 506 | ALUMINIUM STARCH OCTENYLSUCCINATE | Е | The concentration in the medicine must be no more than 7%. |
| 507 | ALUMINIUM STEARATE | Е | Only for use in topical medicines for dermal application. |
| 508 | 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 |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 5%. |
| 509 | AMARANTH | E | Permitted for use only as a colour for oral and topical use. |
| 510 | AMARANTH ALUMINIUM LAKE | E | Permitted for use only as a colour for oral and topical use |
| 511 | AMARANTHUS HYBRIDUS | A, H | |
| 512 | AMARANTHUS RETROFLEXUS | A, H | |
| 513 | 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%. |
| 514 | AMBRETTE SEED OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 515 | AMBRETTOLIDE | E | Permitted for use only in combination with other permitted ingredients as a |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour or a fragrance. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 516 | AMBRINOL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 517 | AMBROSIA ARTEMISIIFOLIA | A, H | |
| 518 | AMBROSIA PSILOSTACHYA | A, H | |
| 519 | 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%. |
| | | | |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 520 | 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%. |
| 521 | 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%. |
| 522 | 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%. |
| 523 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 0.5%. |
| 524 | AMMONIO METHACRYLATE COPOLYMER | E | Only for use in oral medicines. |
| 525 | AMMONIUM ACRYLATES COPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 526 | AMMONIUM ACRYLATES/ACRYLONITROGE NS COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 527 | AMMONIUM ACRYLOYLDIMETHYLTAURAT E/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%. |
| 528 | AMMONIUM ACRYLOYLDIMETHYLTAURAT E/VP COPOLYMER | Е | 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%. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 529 | 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. |
| 530 | AMMONIUM BROMIDE | Н | Only for use as an active homoeopathic ingredient. |
| 531 | AMMONIUM CARBONATE | E, H | Only for use as an active homoeopathic or excipient ingredient. |
| 532 | 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. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 533 | AMMONIUM GLYCYRRHIZINATE | Е | |
| 534 | AMMONIUM IODIDE | Н | Only for use an active ingredient in homoeopathic medicines. |
| 535 | AMMONIUM LACTATE | E | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%. |
| 536 | AMMONIUM LAURETH SULFATE | E | Only for use in topical medicines for dermal application. |
| 537 | AMMONIUM LAURYL SULFATE | E | Only for use in topical medicines for dermal application. |
| 538 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 0.2%. |
| 539 | 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%. |
| 540 | 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%. |
| 541 | AMOMUM AROMATICUM | A, H | |
| 542 | AMOMUM VILLOSUM | A, H | |
| 543 | AMORPHOPHALLUS KONJAC | A, H | Only for use when the dosage form is not tablet. |
| 544 | AMPELODESMOS MAURITANICUS | A, H | |
| 545 | AMPELOPSIS JAPONICA | A, H | |
| 546 | AMYL ACETATE | E | Only for use in topical medicines for dermal |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | application. |
| 547 | 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%. |
| 548 | AMYL BENZOATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 549 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance concentration in a medicine must be no more 1%. |
| 550 | 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%. |
| 551 | 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%. |
| 552 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 553 | 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%. |
| 554 | AMYL ISOBUTYRATE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 555 | AMYL ISOVALERATE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more 1%. |
| 556 | 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%. |
| 557 | 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%. |
| 558 | 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%. |
| 559 | AMYL SALICYLATE | Е | Permitted for use only in combination with other permitted ingredients as a |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 560 | 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%. |
| 561 | 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%. |
| 562 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour concentration in a medicine must be no more than 5%. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 563 | 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. |
| 564 | 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%. |
| 565 | AMYLOPECTIN | Е | Permitted for use only in combination with other |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | permitted ingredients as a flavour. |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 566 | AMYRIS BALSAMIFERA | A, H | |
| 567 | AMYRIS OIL WEST INDIAN | A, E, H | |
| 568 | ANACARDIUM OCCIDENTALE | A, H | |
| 569 | ANACYCLUS PYRETHRUM | A, H | |
| 570 | 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%. |
| 571 | ANAESTHETIC ETHER | Н | Only for use as an active homoeopathic ingredient. |
| 572 | ANAGALLIS ARVENSIS | A, H | |
| 573 | ANAMIRTA COCCULUS | А, Н | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|------------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | mg/L or 0.001%. |
| 574 | ANANAS COMOSUS | A, E, H | |
| 575 | ANAPHALIS SINICA | A, H | |
| 576 | ANDROGRAPHIS PANICULATA | A, H | |
| 577 | ANEMARRHENA ASPHODELOIDES | A, E, H | |
| 578 | ANEMONE ALTAICA | A, H | |
| 579 | ANEMONE CHINENSIS | A, H | |
| 580 | ANEMONE HEPATICA | A, H | |
| 581 | ANEMONE PULSATILLA | A, H | |
| 582 | ANEMONE RADDEANA | A, H | |
| 583 | ANETHOLE | Е | |
| 584 | ANETHOLEA ANISATA | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than |
| 585 586 | ANETHUM GRAVEOLENS ANGELICA ACUTILOBA | A, E, H | 5%. |
| | | A, H | |
| 587 | ANGELICA ANOMALA | A, H | |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 588 | ANGELICA ARCHANGELICA | A, E, H | |
| 589 | ANGELICA ATROPURPUREA | A, H | |
| 590 | ANGELICA DAHURICA | A, E, H | |
| 591 | ANGELICA DECURSIVA | A, H | |
| 592 | ANGELICA POLYMORPHA | A, E, H | |
| 593 | ANGELICA PUBESCENS | A, E, H | |
| 594 | ANGELICA ROOT DRY | A, H | |
| 595 | ANGELICA ROOT OIL | A, E, H | |
| 596 | ANGELICA SEED OIL | A, E, H | |
| 597 | ANGELICA STEM | Е | |
| 598 | ANIBA ROSAEODORA | A, E, H | |
| 599 | ANISALDEHYDE | Е | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 600 | 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 |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | flavour concentration in a medicine must be no more than 5%. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 601 | ANISE OIL | A, E, H | When the concentration of Anise oil in the preparation is more than 50% the nominal capacity of the container must be no more than 50 mL. |
| | | | When the concentration of Anise oil in the preparation is more than 50% and the nominal capacity of the container is 50 mL or less, a restricted flow insert must be fitted on the container. |
| | | | The medicine requires the following warning statement on the medicine label: |
| | | | - (CHILD) 'Keep out of reach of children (or word to that effect)' |
| 602 | 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 |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 5%. |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 603 | ANISEED DRY | A, E, H | |
| 604 | ANISEED POWDER | A, E, H | |
| 605 | 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%. |
| 606 | ANISYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 607 | ANISYL ACETONE | E | Permitted for use only in combination with other |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 608 | 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%. |
| 609 | 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%. |
| 610 | ANNATTO | E | Permitted for use only as a |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | colour for oral and topical use. |
| 611 | ANOGEISSUS LATIFOLIA | A, E, H | |
| 612 | ANTENNARIA DIOICA | A, E, H | |
| 613 | ANTHOCYANINS | Е | |
| 614 | 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%. |
| 615 | ANTHRISCUS CEREFOLIUM | A, H | |
| 616 | ANTHYLLIS VULNERARIA | A, H | |
| 617 | ANTIMONY POTASSIUM TARTRATE TRIHYDRATE | Н | Only for use as an active homoeopathic ingredient. |
| 618 | ANTIMONY TRISULFIDE | Н | Only for use as an active homoeopathic ingredient. |
| 619 | APIUM GRAVEOLENS | A, E, H | |
| 620 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 621 | APOMORPHINE HYDROCHLORIDE HEMIHYDRATE | Н | Only for use as an active homoeopathic ingredient. |
| 622 | APPLE | E | |
| 623 | APPLE CIDER VINEGAR | Е | |
| 624 | APPLE ESSENCE NATURAL | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 625 | APPLE EXTRACT | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 626 | APPLE FIBRE | E | |
| 627 | APRICOT | E | |
| 628 | APRICOT KERNEL OIL PEG-6 ESTERS | E | Only for use as an excipient in topical medicines for dermal application. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 629 | AQUILARIA MALACCENSIS | A, H | |
| 630 | AQUILARIA SINENSIS | A, H | |
| 631 | AQUILEGIA VULGARIS | A, H | |
| 632 | ARACHIDONIC ACID | Е | Only for use in topical medicines for dermal application. |
| 633 | ARACHIDYL ALCOHOL | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. |
| 634 | 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%. |
| 635 | ARACHIDYL PROPIONATE | E | Only for use in topical medicines for dermal application. |
| 636 | ARACHIS HYPOGAEA | A, E, H | The medicine requires the following warning statement |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | on the medicine label: |
| | | | - (PEANUT) 'Contains Peanut' (or words to that effect). |
| 637 | ARACHIS OIL | A, E, H | The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect). |
| 638 | ARALIA CORDATA | A, H | |
| 639 | ARALIA HISPIDA | A, H | |
| 640 | ARALIA NUDICAULIS | A, H | |
| 641 | ARALIA RACEMOSA | A, H | |
| 642 | ARCTIUM LAPPA | A, E, H | |
| 643 | ARCTIUM MINUS | A, H | |
| 644 | ARCTOSTAPHYLOS UVA-URSI | A, E, H | |
| 645 | ARDISIA JAPONICA | A, H | |
| 646 | 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%. |
| 647 | ARGANIA SPINOSA KERNEL OIL | Е | Only for use in topical medicines for dermal |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|---------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 5% in the medicine. |
| 648 | ARGININE | A, E, H | Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (ARGIN1) 'This medicine contains arginine and is intended to be applied to the skin only and not to the mucosa - vagina or rectum.' |
| 649 | 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%. |
| 650 | ARISAEMA ATRORUBENS | А, Н | The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 651 | ARISAEMA CONSANGUINEUM | А, Н | The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 652 | ARISAEMA JAPONICUM | А, Н | The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 653 | 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 more than 20 mg of volatile oil components (of Armoracia rusticana). |
| 654 | ARNEBIA EUCHROMA | A, H | |
| 655 | 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. |
| 656 | ARNICA MOLLIS | A, H | When for use other than topically on unbroken skin, the maximum recommended daily |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 657 | 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. |
| 658 | ARRHENATHERUM ELATIUS | A, H | |
| 659 | ARROWROOT | A, E, H | |
| 660 | ARSENIC TRIIODIDE | Н | Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than 0.001%. |
| 661 | ARSENIC TRIOXIDE | H | Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than 0.001%. |
| 662 | ARTEMISIA ABROTANUM | A, H | Thujone is a mandatory component of Artemisia abrotanum. The concentration of thujone from Artemisia |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | abrotanum in the medicine must be no more than 4%. |
| 663 | 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%. |
| 664 | 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%. |
| 665 | 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%. |
| 666 | ARTEMISIA ARGYI | A, H | Thujone is a mandatory component of Artemisia argyi. The concentration of thujone from Artemisia argyi in the medicine must be no more than |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | 4%. |
| 667 | 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%. |
| 668 | 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%. |
| 669 | ARTEMISIA HERBA-ALBA | A, H | Thujone is a mandatory component of Artemisia herbaalba. The concentration of thujone from Artemisia herba-alba in the medicine must be no more than 4%. |
| 670 | ARTEMISIA MARITIMA | A, H | Thujone is a mandatory component of Artemisia maritima. The concentration of thujone from Artemisia maritima in the |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | medicine must be no more than 4%. |
| 671 | ARTEMISIA OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 672 | 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%. |
| 673 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | |
| 674 | 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%. |
| 675 | ARTERY | Н | Only for use as an active homoeopathic ingredient. |
| 676 | ARTHROSPIRA MAXIMA | A, H | |
| 677 | ARTHROSPIRA PLATENSIS | A, H | |
| 678 | ARUM MACULATUM | А, Н | The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 679 | ASAFOETIDA GUM | A, H | |
| 680 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 681 | ASARUM EUROPAEUM | A, H | |
| 682 | ASARUM HETEROTROPOIDES | A, H | |
| 683 | ASARUM OIL | Е | |
| 684 | ASARUM SIEBOLDII | A, E, H | |
| 685 | ASCLEPIAS TUBEROSA | A, H | |
| 686 | 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 maximum recommended daily dose. |
| 687 | ASCORBIC ACID | A, E | |
| 688 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|----------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 689 | ASCORBYL METHYLSILANOL PECTINATE | Е | Only for use in topical medicines for dermal application. |
| 690 | ASCORBYL PALMITATE | A, E | When for oral use, the maximum recommended daily dose must contain no more than 100mg of ascorbyl palmitate. |
| 691 | 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%. |
| 692 | ASPALATHUS LINEARIS | A, E, H | |
| 693 | ASPARAGINE | A, E | |
| 694 | 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%. |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------------|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 695 | ASPARAGUS | E, H | Only for use as an active homoeopathic or excipient ingredient. |
| 696 | ASPARAGUS COCHINCHINENSIS | А, Н | |
| 697 | ASPARAGUS OFFICINALIS | A, E, H | |
| 698 | ASPARAGUS RACEMOSUS | А, Н | 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. |
| 699 | 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' |
| 700 | ASPARTIC ACID | A, E | |
| 701 | ASPERGILLUS ORYZAE | A, E, H | |
| 702 | ASTAXANTHIN ESTERS EXTRACTED FROM | A | Only for use in oral medicines. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--|---|---|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | HAEMATOCOCCUS PLUVIALIS | | 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). |
| 703 | ASTER NOVI-BELGII | A, H | |
| 704 | ASTER TATARICUS | A, H | |
| 705 | ASTRAGALUS ADSURGENS | A, H | |
| 706 | ASTRAGALUS COMPLANATUS | A, H | |
| 707 | ASTRAGALUS EXCARPUS | A, H | |
| 708 | ASTRAGALUS GUMMIFER | A, E, H | |
| 709 | ASTRAGALUS LENTIGINOSUS | A, H | |
| 710 | ASTRAGALUS MEMBRANACEUS | A, E, H | |
| 711 | ASTRAGALUS PENDULIFLORUS | A, H | |
| 712 | 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%. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| 713 | ATRACTYLODES JAPONICA | A, H | |
| 714 | ATRACTYLODES LANCEA | A, H | |
| 715 | ATRACTYLODES MACROCEPHALA | A, H | |
| 716 | 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%. |
| 717 | ATROPINE SULFATE MONOHYDRATE | Н | Only for use as an active homoeopathic ingredient. |
| 718 | ATTALEA SPECIOSA | E | Only for use in topical medicines for dermal application. |
| 719 | AURA B-AURANTIOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. |

Table 1 Part 2

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 720 | AUREOBASIDIUM PULLULANS | A, H | |
| 721 | AVENA FATUA | A, H | Gluten is a mandatory component of Avena fatua when the plant part is seed and the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect. |
| 722 | 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. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|--------------------------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | to that effect. |
| 723 | AVOCADO | Е | |
| 724 | AVOCADO OIL | Е | |
| 725 | AVOCADO OIL UNSAPONIFIABLES | E | Only for use in topical medicines for dermal application. |
| 726 | AZADIRACHTA INDICA | А, Н | 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: |
| | | | - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that |

| Column 1 | Column 2 | Column 3 | Column 4 |
|----------|-----------------|---|--|
| | Ingredient Name | Purpose of the ingredient in the medicine | Specific requirements(s) applying to the ingredient in Column 2 |
| | | | effect).' - (NTAKEN) 'Not to be taken (or words to that effect).' - (CHILD) 'Keep out of reach of children (or words to that effect).' |
| 727 | AZOVAN BLUE | Е | Permitted for use only as a colour for topical use. |
| 728 | AZULENE | Е | Only for use in topical medicines for dermal application. |