

Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2019

I, Michael Shum, as delegate of the Minister for Health, make the following determination.

Dated 18 April 2019

Michael Shum Acting Assistant Secretary Complementary and Over the Counter Medicines Branch Health Products Regulation Group Department of Health

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Schedule 2—Repeals

| Note: | This instrun | This instrument is in 6 volumes: | |
|-------|--------------|----------------------------------|-----------------------------------------------|
| | Volume 1: | Sections 1-7 | 7 (pages 1-3) |
| | | Schedule 1 | (1,7,7-TRIMETHYLBICYCLO(2.2.1)HEPT-2-YL)- |
| | | | CYCLOHEXANOL)-AZULENE (pages 4-121) |
| | Volume 2: | Schedule 1 | BACKHOUSIA CITRIODORA)–EVERNIA PRUNASTRA |
| | | | EXTRACT (pages 122-380) |
| | Volume 3: | Schedule 1 | FABIANA IMBRICATA–JUSTICIA ADHATODA |
| | | | (pages 381-531) |
| | Volume 4: | Schedule 1 | KADSURA COCCINEA-OYSTER SHELL (pages 532-700) |
| | Volume 5: | Schedule 1 | P-ALPHA-DIMETHYL STYRENE–TYROSINE |
| | | | (pages 701-1005) |
| | Volume 6: | Schedule 1 | UBIDECARENONE-ZUCCHINI (pages 1006-1046) |
| | | Schedule 2 | (page 1047) |

1 Name

This instrument is the *Therapeutic Goods (Permissible Ingredients)* Determination (No. 1) 2019.

2 Commencement

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

| Column 1 | Column 2 | Column 3 |
|---------------------------------|-------------------------------------------------------------|------------------------|
| Provisions | Commencement | Date/Details |
| 1. The whole of this instrument | The day after this instrument is registered. | |
| instrument Note: | This table relates only to the provisions of this instrumen | t as originally made I |

not be amended to deal with any later amendments of this instrument.

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

3 Authority

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

4 Interpretation

Note:

- A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:
 - (a) British Pharmacopoeia;
 - (b) European Pharmacopoeia;
 - (c) medicine;
 - (d) Register; and
 - (e) United States Pharmacopeia-National Formulary.
- (1) In this instrument:

Act means the Therapeutic Goods Act 1989.

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

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

excipient or *E*, for a medicine, means an ingredient that is not an active ingredient or a homoeopathic preparation ingredient.

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

homoeopathic preparation has the same meaning as in the Regulations.

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

Regulations means the *Therapeutic Goods Regulations* 1990.

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

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

- (2) To avoid doubt, the terms set out in closed brackets in column 4 of the table in Schedule 1 to this instrument, which are associated with warning statements in relation to particular ingredients, are:
 - (a) terms from the code tables under the headings *Indications* or *Product Warning*; and
 - (b) not required to be reproduced in a warning statement on the label of a medicine.
 - Note: Examples of these terms include the following:
 - (a) (ARGIN1);
 - (b) (CHILD3);
 - (c) (GLUTEN);
 - (d) (PEANUT); and
 - (e) (PREGNT).

5 Permissible ingredients

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

6 Requirements in relation to permissible ingredients being contained in medicine

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

- (a) the ingredient must only be used in a medicine for a purpose specified in relation to the ingredient in column 3 of that item;
- (b) the ingredient must comply with the requirements specified in relation to the ingredient in column 4 of that item;
- (c) if the ingredient is derived from animal origin—the safety of the ingredient must have been assessed against, and comply with, the principles and requirements in the European Pharmacopoeia general monograph 1483 *Products with risk of transmitting agents of animal spongiform encephalopathies*, including General Text 5.2.8: *Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products*.

7 Repeals

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

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

Note: See sections 5 and 6.

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

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| 5 | (E)-2-(3,5-DIMETHYLHEX-3-EN-2- YLOXY)-2-METHYLPROPYL CYCLOPROPANECARBOXYLATE | Ε | Permitted for use only in combination with 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 | 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%. |
| 7 | (E, E)-2,6-NONADIENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 0 | | | |
| 89 | (S)-LACTIC ACID (S)-S-ADENOSYLMETHIONINE DISULFATE DITOSYLATE DIHYDRATE | A, E, H A | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that |

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| | | | effect)' |
|----|----------------------------------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10 | (S)-S-ADENOSYLMETHIONINE DISULFATE TOSYLATE | A | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tosylate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warnin 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 healthcarp 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 healthcar practitioner (or words to that effect)' |
| 12 | (S)-S-ADENOSYLMETHIONINE HEXASULFATE DIHYDRATE | Α | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine hexasulfate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warnin statement on the medicine |

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| | | | label: - (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
|----|----------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 13 | (S)-S-ADENOSYLMETHIONINE 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)' |
| 14 | (S)-S-ADENOSYLMETHIONINE PENTASULFATE DIHYDRATE | А | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine pentasulfate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: -(SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |

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| 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 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)' |
|----|-----------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 17 | (S)-S-ADENOSYLMETHIONINE TETRATOSYLATE DIHYDRATE | A | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine tetratosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: |

| | | | - (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
|----|----------------------------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 18 | (S)-S-ADENOSYLMETHIONINE TRISULFATE DITOSYLATE DIHYDRATE | A | (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine trisulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 19 | (Z)-HEX-3-ENYL 2- ETHYLBUTYRATE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 20 | (Z, Z)-3,6-NONADIEN-1-OL | 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%. |

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| 21 | (±)-NARINGENIN | 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%. |
|----------|--------------------------------------------------------------------------------------------|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 22 | 1,1,1-TRICHLOROETHANE | Е | The concentration in the medicine must be no more than 25%. |
| 23 | 1,2-HEXANEDIOL | Е | Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye. The concentration in the medicine must be no more than 1%. |
| 24 | 1,3,4,6,7,8A-HEXAHYDRO-1,1,5,5- TETRAMETHYL-2H-2,4A- METHANONAPHTHALEN-8(5H)- ONE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 25 | 1,3,5-UNDECATRIENE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 26 | | Б | |
| 26 27 | 1,3-BUTYLENE GLYCOL 1,3-NONANEDIOL ACETATE, MIXED ESTERS | E E | Permitted for use only in combination with other permitted ingredients as a |

| | | | flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
|----|----------------------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 28 | 1,3-NONANEDIOL, DIACETATE | 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%. |
| 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 medicine must be no more than 1%. |
| 31 | 1,5,9-TRIMETHYL-13- OXABICYCLO[10.1.0]TRIDECA-4,8- DIENE | 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%. |

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| 32 | 1,7,7- TRIMETHYLBICYCLO[4.4.0]DECAN -3-YL ACETATE | Ε | Permitted for use only in combination with 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-3- 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%. |
| 35 | 1-(3,3- DIMETHYLCYCLOHEXYL)ETHYL FORMATE | 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%. |
| 36 | 1-(4- ISOPROPYLCYCLOHEXYL)ETHAN 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%. |
| 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. |

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| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
|----|------------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 38 | 1-DODECANOL | Ε | 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 | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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 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- | Е | Permitted for use only in combination with other |

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| | YL)METHYL]- CYCLOPROPANEMETHANOL | | 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 | 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%. |
| 44 | 1-METHYL-4-(4-METHYL-3- PENTENYL)-3-CYCLOHEXENE-1- CARBOXALDEHYDE | 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%. |
| 45 | 1-OCTEN-3-ONE | Ε | Permitted for use only in combination with 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 | 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%. |
| 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 |

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

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| | | | 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 | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 55 | 2,2-DIMETHYL-5-(1- METHYLPROPEN-1-YL) TETRAHYDROFURAN | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 56 | 2,2-DIMETHYL-P-ETHYLPHENYL- PROPANENITRILE | 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 | 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%. |

| 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 | 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%. |
| 60 | 2,3-DIETHYLPYRAZINE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 61 | 2,3-DIHYDRO-1,1-DIMETHYL-1H- INDENE-AR-PROPANAL | E | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient. The total fragrance proprietary excipient formulation concentration in a medicine must not be more than 1%. |
| 62 | 2,3-DIHYDRO-2,5-DIMETHYL-1H- INDENE-2-METHANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 63 | 2,3-DIMETHYLPYRAZINE | Е | Permitted for use only in combination with other permitted ingredients as a |

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| | | | flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
|----|------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 64 | 2,3-HEXADIONE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 65 | 2,3-HEXANEDIONE | 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%. |
| 66 | 2,3-PENTANEDIONE | 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%. |
| 67 | 2,4,5-TRIMETHYLTHIAZOLE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 68 | 2,4,6-TRIMETHYL-4-PHENYL-1,3- DIOXANE | 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%. |
|----|----------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 69 | 2,4-DECADIENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 3 mg of 2,4-Decadienal. |
| 70 | 2,4-DIMETHYL BUTADIENEACROLEIN | 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%. |
| 71 | 2,4-DIMETHYL THIAZOLE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 72 | 2,4-DIMETHYL-3-CYCLOHEXENE CARBOXALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 73 | 2,4-DIMETHYL-4,4A,5,9B- TETRAHYDROINDENO[1,2-D]-1,3- DIOXIN | 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%. |
|----|-------------------------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 74 | 2,4-DIMETHYL-4-PHENYL TETRAHYDROFURAN | 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%. |
| 75 | 2,4-HEPTADIENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 3 mg of 2,4-Heptadienal. |
| 76 | 2,4-HEXADIENOL | 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 the medicine must be no more than 1%. The maximum daily dose must provide no more than |

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| | | | 13.5 mg of 2,4-Hexadienol. |
|----|-------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 77 | 2,5-DIETHYLTETRAHYDROFURAN | 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%. |
| 78 | 2,5-DIMETHYL-2-OCTEN-6-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%. |
| 79 | 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%. |
| 80 | 2,5-DIMETHYL-4-METHOXY-3(2H)- 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%. |
| 81 | 2,5-DIMETHYLPYRAZINE | Е | 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 |

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| | | | 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% |
|----|--------------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 82 | 2,6,6,TRIMETHYL-2- CYCLOHEXENE-1,4-DIONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 83 | 2,6,9,10-TETRAMETHYL-1- OXASPIRO(4.5)DECA-3,6-DIENE | 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%. |
| 84 | 2,6-DIMETHOXYPHENOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 85 | 2,6-DIMETHYL HEPTAN-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 |

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

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| | | | permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
|----|--------------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 91 | 2,6-OCTADIENOIC ACID, 3,7- DIMETHYL-, METHYL ESTER, (2E)- | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 92 | 2-(1,1-DIMETHYLETHYL)-1,4- DIMETHOXY-BENZENE | 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%. |
| 93 | 2-(2-(4-METHYL-3-CYCLOHEXEN-1- YL)PROPYL CYCLOPENTANONE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 94 | 2-(2-METHYLPHENYL)ETHANOL | Е | 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 |

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| | | | than 1%. |
|-----|-----------------------------------------------------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 95 | 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%. |
| 96 | 2-[1-(3,3- DIMETHYLCYCLOHEXYL)ETHOXY]-2-METHYLPROPYL] CYCLOPROPANECARBOXYLATE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 97 | 2-[1-(3,3- DIMETHYLCYCLOHEXYL)ETHOXY]-2-OXOETHYL PROPANOATE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 98 | 2-ACETYLFURAN | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 99 | 2-ACETYLPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 100 | 2-ACETYLPYRIDINE | E | Permitted for use only in combination with other |

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| | | | permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
|-----|----------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 101 | 2-AMINO-2-METHYL-1-PROPANOL | E | Only for use in topical medicines for dermal application. |
| 102 | 2-BENZYL-4,4,6-TRIMETHYL-1,3- DIOXANE | 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%. |
| 103 | 2-BUTEN-1-OL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 104 | 2-BUTYL-4,4,6-TRIMETHYL-1,3- DIOXANE | 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-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 |

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| | | | medicine must be no more than 1%. |
|-----|---------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 106 | 2-DECENAL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 107 | 2-DODECANOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 108 | 2-DODECENAL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 109 | 2-ETHOXY-4-(METHOXYMETHYL)- PHENOL | 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%. |
| 110 | 2-ETHOXYETHANOL | Е | The residual solvent limit for 2-Ethoxyethanol is 1.6 mg pe |

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| | | | maximum recommended daily dose. The concentration in the medicine must be no more than 0.016%. |
|-----|------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 111 | 2-ETHYL-1-HEXANOL | 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%. |
| 112 | 2-ETHYL-3,5-DIMETHYLPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 113 | 2-ETHYL-3,6-DIMETHYLPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 114 | 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%. |

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| 115 | 2-ETHYL-4-(2,2,3-TRIMETHYL-3- CYCLOPENTEN-1-YL)-2-BUTEN-1- OL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
|-----|---------------------------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 116 | 2-ETHYL-4-HYDROXY-5-METHYL- 3(2H)-FURANONE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 117 | 2-ETHYL-4-METHYLTHIAZOLE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 118 | 2-ETHYL-ALPHA,ALPHA- DIMETHYL-BENZENEPROPANAL | 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%. |
| 119 | 2-ETHYLBUTYRIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour. |

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| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
|-----|-------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 120 | 2-HEPTANOL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 121 | 2-HEPTANONE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 122 | 2-HEPTYL CYCLOPENTANONE | 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%. |
| 123 | 2-HEXENYL ACETATE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |

| 124 | 2-HYDROXYACETOPHENONE | Ε | 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%. |
|-----|-----------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 125 | 2-ISOBUTYL-3- METHOXYPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 126 | 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%. |
| 127 | 2-ISOPROPOXYETHYL SALICYLATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 128 | 2-ISOPROPYL-4-METHYLTHIAZOLE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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| 129 | 2-MERCAPTOPROPIONIC ACID | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
|-----|----------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 130 | 2-METHOXY-3- SECBUTYLPYRAZINE | 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%. |
| 131 | 2-METHOXY-4-VINYLPHENOL | 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%. |
| 132 | 2-METHYL BUTYRIC ACID | 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%. |
| 133 | 2-METHYL HEPTANOIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

| 134 | 2-METHYL-2-PENTENOIC ACID | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
|-----|-------------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 135 | 2-METHYL-2-VINYL-5- ISOPROPENYLTETRAHYDROFURA N | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 136 | 2-METHYL-3-(3,4- METHYLENEDIOXYPHENYL)PROP ANAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 137 | 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%. |
| 138 | 2-METHYL-3-[4-(2- METHYLPROPYL)PHENYL]PROPAN AL | 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%. |

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| 139 | 2-METHYL-3-BUTEN-2-OL | Ε | Permitted for use only in combination with 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-3-FURANTHIOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 141 | 2-METHYL-4-(2,2,3-TRIMETHYL-3- CYCLOPENTEN-1-YL)BUTANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 142 | 2-METHYL-4-(2,2,3-TRIMETHYL-3- CYCLOPENTENYL)-2-BUTEN-1-OL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. Only for use in topical medicines for dermal application. |
| 143 | 2-METHYL-4-(2,6,6-TRIMETHYL-1- CYCLOHEXEN-1-YL)-2-BUTENAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

| 144 | 2-METHYL-4-(CAMPHENYL-8)- CYCLOHEXANONE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
|-----|--------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 145 | 2-METHYL-4-PROPYL-1,3- OXTHIANE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 146 | 2-METHYL-5- (METHYLTHIO)FURAN | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 147 | 2-METHYL-5-PHENYLPENTANOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 148 | 2-METHYLBUTYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 149 | 2-METHYLBUTYL ISOVALERATE | Е | Permitted for use only in combination with other permitted ingredients as a |

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| | | | flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
|-----|------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 150 | 2-METHYLBUTYL PHENYLETHYL ETHER | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 151 | 2-METHYLBUTYL SALICYLATE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 152 | 2-METHYLHEXANOIC ACID | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 153 | 2-METHYLPYRAZINE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the tota fragrance concentration in a medicine must be no more 1%. |
| 154 | 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%. |
|-----|----------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 155 | 2-METHYLUNDECANAL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 156 | 2-METHYLVALERIC 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%. |
| 157 | 2-NONENAL | 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%. |
| 158 | 2-NONENENITRILE | 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%. |

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| 159 | 2-OXOBUTYRIC ACID | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
|-----|-------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 160 | 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%. |
| 161 | 2-PENTANOL | 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%. |
| 162 | 2-PENTANONE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 163 | 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%. |
| 164 | 2-PENTYL FURAN | E | Permitted for use only in combination with other |

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

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

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| 173 | 2-TRIDECENAL | 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%. |
|-----|---------------------------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 174 | 2-TRIDECENENITRILE | 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%. |
| 175 | 2-UNDECENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 176 | 3,3-DIMETHYL-5-(2,2,3- TRIMETHYL-3-CYCLOPENTEN-1- YL)-4-PENTEN-2-OL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 177 | 3,3-DIMETHYLACRYLIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

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| 178 | 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 tota fragrance concentration in a medicine must be no more than 1%. |
|-----|----------------------------------------------------------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 179 | 3,4-DIMETHYL-1,2- CYCLOPENTADIONE | 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%. |
| 180 | 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 tota fragrance concentration in a medicine must be no more than 1%. |
| 181 | 3,5,5-TRIMETHYLHEXYL ACETATE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 182 | 3,5,6,6-TETRAMETHYL-4- METHYLENEHEPTAN-2-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 183 | 3,5-DIMETHOXYTOLUENE | 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%. |
|-----|-------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 184 | 3,5-DIMETHYL-3-CYCLOHEXENE-1- CARBOXALDEHYDE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 185 | 3,6-DIMETHYL-3-CYCLOHEXENE-1- CARBOXALDEHYDE | 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%. |
| 186 | 3,7-DIMETHYL OCTANAL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 187 | 3,7-DIMETHYL-1-OCTANOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 188 | 3,7-DIMETHYL-2,6- NONADIENENITRILE | Е | Permitted for use only in combination with other permitted ingredients as a |

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| | | | fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
|-----|--------------------------------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 189 | 3,7-DIMETHYL-7- METHOXYOCTAN-2-OL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 190 | 3-(3-ISOPROPYLPHENYL)BUTANAL | 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%. |
| 191 | 3-(4-ETHYLPHENYL)-2,2- DIMETHYLPROPANAL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 192 | 3-(4-HYDROXYPHENYL)-1-(2,4,6- TRIHYDROXYPHENYL)-1- PROPANONE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 193 | 3-(4-TERT-BUTYLPHENYL)- PROPANAL | 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 |

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| | | | than 1%. |
|-----|------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 194 | 3-(ISO-CAMPHYL-5)- CYCLOHEXANOL | 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%. |
| 195 | 3-(METHYLTHIO)-1-HEXYL ACETATE | 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%. |
| 196 | 3-CARENE | 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%. |
| 197 | 3-DODECENAL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 198 | 3-ETHYLPYRIDINE | 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 |

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| | | | than 5%. |
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| 199 | 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%. |
| 200 | 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%. |
| 201 | 3-HEXEN-1-OL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 202 | 3-ISO-CAMPHYL-5-CYCLOHEXAN- 1-OL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 203 | 3-METHYL THIOPROPIONALDEHYDE ETHANOL | 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 |

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| | | | than 5%. |
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| 204 | 3-METHYL-2- (PENTYLOXY)CYCLOPENT-2-EN-1- ONE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 205 | 3-METHYL-5-(2,2,3-TRIMETHYL-3- CYCLOPENTEN-1-YL)-4-PENTEN-2- OL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 206 | 3-METHYL-5-PHENYL PENT-2- ENENITRILE | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 207 | 3-METHYL-5-PHENYLPENTANAL | Е | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 208 | 3-METHYL-5- PHENYLPENTANENITRILE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 209 | 3-METHYL-5-PHENYLPENTANOL | Е | Permitted for use only in combination with other |

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| | | | permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
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| 210 | 3-METHYL-5-PROPYL-2- CYCLOHEXEN-1-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 211 | 3- METHYLCYCLOPENTADECANONE | 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%. |
| 212 | 3- METHYLCYCLOPENTADECENONE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 213 | 3-METHYLTHIOHEXANOL | 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%. |
| 214 | 3-OCTANOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a |

| | | | medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
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| 215 | 3-OCTYL ACETATE | 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%. |
| 216 | 3-PENTYLTETRAHYDRO-2H- PYRAN-4-OL ACETATE | 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%. |
| 217 | 3-PHENYLPROPIONALDEHYDE | 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%. |
| 218 | 3-PHENYLPROPYL 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 |

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| | | | medicine must be no more 1%. |
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| 219 | 3-PHENYLPROPYL PROPIONATE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 220 | 3-PROPYLIDENE PHTHALIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 221 | 3-TRANS- ISOCAMPHYLCYCLOHEXANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 222 | 3A,6,6,9A- TETRAMETHYLDODECAHYDRONA PHTHO[2,1-B] FURAN | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 223 | 4,4A,5,9B-TETRAHYDRO-2,4- DIMETHYL-INDENO(1,2-D)-1,3- DIOXIN | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a |

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| | | | medicine must be no more than 1%. |
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| 224 | 4,4A,5,9B- TETRAHYDROINDENO(1,2-D)-1,3- DIOXIN | 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%. |
| 225 | 4,5-DIMETHYL-3-HYDROXY- 2(5H)FURANONE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 226 | 4,7-METHANO-1H- INDENEMETHANOL, OCTAHYDRO- , ACETATE | Ε | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 227 | 4,7-METHANO-3A,4,5,6,7,7A- HEXAHYDRO-5 (OR 6) -INDENYL ACETATE | 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%. |
| 228 | 4,8-DIMETHYL-3,7-NONADIEN-2-OL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 229 | 4-(4-HYDROXY-4- METHYLPENTYL)-3- CYCLOHEXENE CARBOXALDEHYDE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
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| 230 | 4-(4-METHYL-3-PENTEN-1-YL)-3- CYCLOHEXENE-1- CARBOXALDEHYDE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 231 | 4-(5,5,6- TRIMETHYLBICYCLO(2.2.1)HEPT-2- YL)-CYCLOHEXANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 232 | 4-(METHYLTHIO)-4-METHYL-2- PENTANONE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 233 | 4-(PARA-HYDROXYPHENYL)-2- BUTANONE | 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%. |
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| 234 | 4-(PARA-METHOXYPHENYL)-2- BUTANONE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 235 | 4-ACETYL-6-TERTIARY-BUTYL-1,1- DIMETHYLINDAN | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 236 | 4-ETHYL GUAIACOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 237 | 4-HEPTANONE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |

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| 238 | 4-HYDROXYBENZALDEHYDE | 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%. |
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| 239 | 4-HYDROXYBENZYL ALCOHOL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 240 | 4-ISOPROPYL-3-METHYLPHENOL | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%. |
| 241 | 4-METHOXY-2-METHYL-2- BUTANETHIOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 242 | 4-METHYL-3-DECEN-5-OL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 243 | 4-METHYL-4-MERCAPTOPENTAN- 2-ONE | Е | Permitted for use only in combination with other permitted ingredients as a flavour. |

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| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
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| 244 | 4-METHYL-4-PHENYL-2-PENTYL ACETATE | 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%. |
| 245 | 4-METHYL-5-THIAZOLETHANOL | 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%. |
| 246 | 4-METHYLBENZYLIDENE CAMPHOR | Α | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must 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). |

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| | | | 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). |
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| 247 | 4-METHYLPENTANOIC ACID | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 248 | 4-METHYLPHENYL OCTANOATE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 249 | 4-PARA METHOXYPHENYL-3- BUTANONE | 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%. |
| 250 | 4-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%. |
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| 251 | 4-TERT-BUTYL-2,6-DIMETHYL ACETOPHENONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 252 | 4-TERT-BUTYLCYCLOHEXANOL | E | Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%. |
| 253 | 4-TERT-PENTYLCYCLOHEXANONE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 254 | 5,6,7,8- TETRAHYDROQUINOXALINE | 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%. |
| 255 | 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 |

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| | | | medicine must be no more than 5%. |
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| 256 | 5-(2,2,3-TRIMETHYL-3- CYCLOPENTEN-1-YL)-3- METHYLPENTAN-2-OL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 257 | 5-ACETYL-1,1,2,3,3,6- HEXAMETHYL INDAN | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 258 | 5-CYCLOHEXADECEN-1-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 259 | 5-ETHYL-3-HYDOXY-4-METHYL- 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 medicine must be no more than 5%. |
| 260 | 5-ETHYL-4-HYDROXY-2-METHYL- 3(2H)-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 |

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| | | | medicine must be no more than 5%. |
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| 261 | 5-HYDROXY-4-METHYLHEXANOIC ACID DELTA-LACTONE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 262 | 5-METHOXYPSORALEN | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 263 | 5-METHYL 2-PHENYL HEXEN-2-AL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 264 | 5-METHYL-2-THIOPHENE CARBOXALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 265 | 5-METHYL-3- BUTYLTETRAHYDROPYRAN-4-YL ACETATE | 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%. |
| 266 | 5-METHYL-3-HEPTANONE OXIME | Е | Permitted for use only in |

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

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| 275 | 6-METHYL-2-BUTEN-3-OL-2 | Е | |
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| 276 | 7-ACETYL-1,1,3,4,4,6- HEXAMETHYL TETRAHYDRONAPHTHALENE | 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%. |
| 277 | 7-METHYL-2H-1,5- BENZODIOXEPIN-3(4H)-ONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 278 | 7-OCTENE-1,6-DIOL, 3,7- DIMETHYL- | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 279 | 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%. |
| 280 | 8,13:13,20-DIEPOXY-14,15- BISNORLABDANE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more |

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| | | | than 1%. |
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| 281 | 8-METHYL-1- OXASPIRO(4,5)DECAN-2-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 282 | 8-OCIMENYL ACETATE | 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%. |
| 283 | 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%. |
| 284 | ABELMOSCHUS MOSCHATUS | A, H | |
| 285 | ABELMOSCHUS MOSCHATUS ABELMOSCHUS MOSCHATUS SUBSP. MOSCHATUS | A, H A, H | |
| 286 | ABIES BALSAMEA | A, H | |
| 287 | ABIES NIGRA | A, H | |
| 288 | ABIES PECTINATA | A, H | |
| 289 | ABIES SIBIRICA | A, H | |
| 290 | ABRUS CANTONIENSIS | Α, Η | 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. |
| 291 | ABUTILON THEOPHRASTI | A, H | |
| 292 | ACACIA | A, E, H | |
| 293 | ACACIA BAILEYANA | A, H | |
| 294 | ACACIA CATECHU | A, H | |
| 295 | ACACIA DEALBATA | A, H | |

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| 296 | ACACIA DECURRENS | 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%. |
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| 297 | ACACIA FARNESIANA | 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%. |
| 298 | ACACIA LONGIFOLIA | A, E, H | |
| 299 | ACACIA NILOTICA | A, E, H | |
| 300 | ACACIA SENEGAL | A, E, H | |
| 301 | ACALYPHA INDICA | A, H | |
| 302 | ACANTHUS MOLLIS | A, H | |
| 303 | ACER CAMPESTRE | A, H | |
| 304 | ACER NEGUNDO | A, H | |
| 305 | ACER SACCHARINUM | A, H | |
| 306 | ACER SACCHARUM | A, E, H | |
| 307 | ACEROLA | Е | |
| 308 | ACESULFAME POTASSIUM | Е | |
| 309 | ACETAL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 310 | ACETALDEHYDE | 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%. |
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| 311 | ACETALDEHYDE ETHYL LINALYL ACETAL | 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%. |
| 312 | ACETALDEHYDE ETHYL PHENYLETHYL ACETAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 313 | ACETALDEHYDE PHENYLETHYL PROPYL ACETAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%. |
| 314 | ACETANISOLE | E | Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. |
| 315 | ACETIC ACID | E, H | The concentration in the medicine must be no more |

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| | | | than 80%. |
|-----|------------------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 316 | ACETOIN | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 317 | ACETOMENAPHTHONE | A, E | |
| 318 | ACETONE | Е | The residual solvent limit for Acetone is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%. |
| 319 | ACETOPHENONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 320 | ACETOVANILLONE | E | Only for use in topical medicines for dermal application. Permitted for use only in combination with other permitted ingredients as a fragrance. If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

| 321 | ACETYL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
|-----|-------------------------------------------------|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 322 | ACETYL DIPEPTIDE-1 CETYL ESTER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%. |
| 323 | ACETYL GLUCOSAMINE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%. If the ingredient is sourced from seafood, then the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood' |
| 324 | ACETYL HEXAMETHYL TETRALIN | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 325 | ACETYL LEVOCARNITINE HYDROCHLORIDE | A, E | |
| 326 | ACETYL TRIFLUOROMETHYLPHENYL VALYLGLYCINE | Ε | Only for use in topical medicines for dermal application and not to be included in medicines |

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| | | | intended for use in the eye. The concentration in the medicine must be no more than 0.5%. |
|------------|----------------------------------------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 327 | ACETYLATED LANOLIN | E | Only for use in topical medicines for dermal application. |
| 328 | ACETYLATED LANOLIN ALCOHOL | Е | Only for use in topical medicines for dermal application. |
| 329 | ACETYLATED MONOGLYCERIDES | Е | |
| 330 | ACETYLATED VETIVER OIL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 331 | ACETYLCYSTEINE | Ε | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.001%. |
| 332 | ACHILLEA ERBA-ROTTA SUBSP. MOSCHATA | A, H | |
| 333 | ACHILLEA MILLEFOLIUM | А, Е, Н | Arbutin is a mandatory component of Achillea millefolium. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used or the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %. |
| 334 | ACHILLEA PTARMICA | A, H | |
| 335 | ACHYRANTHES ASPERA | A, H | |
| 226 | ACHYRANTHES BIDENTATA | A, H | |
| 336 337 | ACHYRANTHES FAURIEI | A, H | |

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| 338 | ACID GREEN 25 | Е | Permitted for use only as a colour for topical use. |
|-----|-----------------------------------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 339 | ACID RED 33 | Е | Permitted for use only as a colour for topical use. |
| 340 | ACID RED 87 | E, H | Only for use as an active homoeopathic ingredient or for excipient use as a colour in topical medicines. |
| 341 | ACID TREATED WAXY MAIZE STARCH | Е | |
| 342 | ACID-ISOMERISED LINALOOL | Ε | 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%. |
| 343 | ACONITUM CARMICHAELII | A, H | Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum carmichaelii. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack. |
| 344 | ACONITUM FEROX | А, Н | Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum ferox. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack. |
| 345 | ACONITUM KUSNEZOFFI | А, Н | 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. |

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| 346 | ACONITUM NAPELLUS | А, Н | 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. |
|-----|-----------------------------------------------------------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 347 | ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER | Ε | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.7%. |
| 348 | ACRYLAMIDES COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 349 | ACRYLATES COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 350 | ACRYLATES/ACRYLAMIDE COPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 351 | ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER | E | Only for use in topical medicines for dermal application. |
| 352 | ACRYLATES/C12-22 ALKYL METHACRYLATE COPOLYMER | Ε | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. |
| 353 | ACRYLATES/DIMETHICONE COPOLYMER | 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 2%. |
|-----|-------------------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 354 | ACRYLATES/OCTYLACRYLAMIDE COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 355 | ACRYLATES/STEARETH-20 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 medicine must be no more than 1%. |
| 356 | ACRYLATES/VA COPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 357 | ACRYLIC ACID/VP CROSSPOLYMER | Ε | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%. |
| 358 | ACTAEA CIMICIFUGA | A, H | |
| 359 | ACTAEA HERACLEIFOLIA | A, H | |
| 360 | ACTAEA PACHYPODA | A, H | |
| 361 | ACTAEA RACEMOSA | А, Н | 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.' |

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| 362 | ACTAEA SIMPLEX | А, Н | |
|-----|------------------------------------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 363 | ACTAEA SPICATA | A, H | |
| 364 | ACTINIDIA CHINENSIS | A, H | |
| 365 | ACTINIDIA DELICIOSA | A, H | |
| 366 | ACTIVATED ATTAPULGITE | Α | When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. |
| 367 | ACTIVATED CHARCOAL | A, E, H | When for internal use, the medicine requires the following warning statement on the medicine label: - (ACCOAL) 'Products containing activated charcoal should be used with caution in children since it may interfere with absorption of nutrients. Activated charcoal may interact with other medicines. Activated charcoal is not recommended for long-term use' (or words to that effect). |
| 368 | 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 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)' |

| 369 | ADEMETIONINE DISULFATE TOSYLATE | А, Н | (S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tosylate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
|-----|-------------------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 370 | ADEMETIONINE DISULFATE TRITOSYLATE DIHYDRATE | А, Н | (S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tritosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine 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)' |
| 371 | 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 |

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| | | | are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
|-----|-----------------------------------------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 372 | ADEMETIONINE HEXATOSYLATE DIHYDRATE | А, Н | (S)-S-Adenosylmethionine is a mandatory component of Ademetionine hexatosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 373 | ADEMETIONINE PENTASULFATE DIHYDRATE | А, Н | (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)' |
| 374 | ADEMETIONINE PENTATOSYLATE DIHYDRATE | A, H | (S)-S-Adenosylmethionine is a mandatory component of Ademetionine pentatosylate |

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| | | | 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 TETRASULFATE DIHYDRATE | А, Н | (S)-S-Adenosylmethionine is a mandatory component of Ademetionine tetrasulfate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 376 | 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 anti- depressants or suffer from bipolar depression should not |

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| | | | use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
|-----|-------------------------------------------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 377 | ADEMETIONINE TRISULFATE DITOSYLATE DIHYDRATE | А, Н | (S)-S-Adenosylmethionine is a mandatory component of Ademetionine trisulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)' |
| 378 | ADENOPHORA STRICTA | A, H | |
| 379 | ADENOPHORA TRIPHYLLA | A, H | |
| 380 | ADENOSINE | Ε | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.04%. |
| 381 | ADENOSINE PHOSPHATE | Ε | 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%. |
| 382 | ADENOSINE TRIPHOSPHATE | Е | Only for use in topical medicines for dermal application. |

| 383 | ADENOSINE TRIPHOSPHATE DISODIUM | Ε | Only for use in topical medicines for dermal application. |
|-----|-----------------------------------------------------------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 384 | ADIANTUM CAPILLUS-VENERIS | A, H | |
| 385 | ADIPIC ACID | Е | |
| 386 | ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER | Ε | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. |
| 387 | ADONIS VERNALIS | А, Н | The concentration of equivalent dry Adonis vernalis in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 388 | ADRENALINE (EPINEPHRINE) | Н | Only for use as an active homoeopathic ingredient. |
| 389 | ADZUKI BEAN | Е | |
| 390 | AEGOPODIUM PODAGRARIA | А, Н | |
| 391 | AESCULUS CHINENSIS | А, Н | |
| 392 | AESCULUS GLABRA | А, Н | |
| 393 | AESCULUS HIPPOCASTANUM | А, Н | |
| 394 | AESCULUS X CARNEA | A, H | |
| 395 | AETHUSA CYNAPIUM | Н | Only for use as an active homoeopathic ingredient. |
| 396 | AGAR | A, E | |
| 397 | AGASTACHE RUGOSA | A, H | |
| 398 | AGATHOSMA BETULINA | A, E, H | Pulegone is a mandatory component of Agathosma betulina. The concentration of pulegone in the medicine must be no more than 4%. |
| 399 | AGAVE AMERICANA | А, Е, Н | |
| 400 | AGRIMONIA EUPATORIA | А, Е, Н | |
| 401 | AGRIMONIA REPENS | A, H | |
| 402 | AGROSTIS TENUIS | A, H | |
| 403 | AILANTHUS ALTISSIMA | A, H | |
| 404 | AJUGA CHAMAEPITYS | A, H | |

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| 405 | AJUGA REPTANS | А, Н | |
|-----|---------------------------------------------------|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 406 | ALANINE | A, E | |
| 407 | ALANYLGLUTAMINE | А | Only for use in oral medicines. |
| 408 | ALARIA ESCULENTA | А, Н | Iodine is a mandatory component of Alaria esculenta. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 409 | ALBIZIA JULIBRISSIN | A, H | |
| 410 | ALBIZIA LEBBECK | A, H | |
| 411 | ALCEA ROSEA | A, H | |
| 412 | ALCHEMILLA ALPINA | A, H | |
| 413 | ALCHEMILLA ARVENSIS | A, H | |
| 414 | ALCHEMILLA VULGARIS | A, H | |
| 415 | ALETRIS FARINOSA | A, H | |
| 416 | ALETRIS SPICATA | A, H | |
| 417 | ALEURITES MOLUCCANUS SEED OIL | E | Only for use in topical medicines for dermal application. |
| 418 | ALFADEX | Α, Ε | Only for use in oral medicines. The maximum daily dose must provide no more than 6 g of alfadex. |
| 419 | ALGINATE-KONJAC-XANTHAN POLYSACCHARIDE COMPLEX | A | Only for use in oral medicines. Only for use when the dosage form is other than tablet. The maximum recommended daily dose must be no more than 13.5 g. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the |

medicine requires the following warning statement on the medicine label: -(SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' 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).

| 420 | ALGINIC ACID | Е | |
|-----|--------------------------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 421 | ALISMA ORIENTALE | A, H | |
| 422 | ALISMA PLANTAGO AQUATICA | A, H | |
| 423 | ALKANNA TINCTORIA | A, H | |
| 424 | ALKYL (C12-15) BENZOATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 21%. |
| 425 | ALLANTOIN | Е | Only for use in topical medicines for dermal application. |
| 426 | ALLIARIA PETIOLATA | A, H | |
| 427 | ALLIUM CEPA | A, H | |
| 428 | ALLIUM FISTULOSUM | A, H | |
| 429 | ALLIUM HIEROCHUNTINUM | A, H | |
| 430 | ALLIUM MACROSTEMON | A, H | |
| 431 | ALLIUM ODORUM | A, H | |
| 432 | ALLIUM PORRUM | A, H | |
| 433 | ALLIUM SATIVUM | A, E, H | |
| 434 | ALLIUM SCHOENOPRASUM | A, H | |
| 435 | ALLIUM URSINUM | A, H | |
| 436 | ALLO-OCIMENE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total |

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| | | | fragrance concentration in a medicine must be no more than 1%. |
|-----|---------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 437 | ALLURA RED AC | Е | Permitted for use only as a colour for oral and topical use |
| 438 | ALLURA RED AC ALUMINIUM LAKE | Е | Permitted for use only as a colour for oral and topical use |
| 439 | ALLYL ALPHA-IONONE | 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%. |
| 440 | ALLYL AMYL GLYCOLATE | 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%. |
| 441 | ALLYL CAPRYLATE | 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%. |
| 442 | ALLYL CYCLOHEXANEPROPIONATE | 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%. |
|-----|-------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 443 | ALLYL CYCLOHEXYLOXYACETATE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 444 | ALLYL HEPTANOATE | 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%. |
| 445 | 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%. |
| 446 | ALLYL HEXANOATE | 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 |

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| | | | fragrance concentration in a medicine must be no more 1%. |
|-----|----------------------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 447 | ALLYL ISOTHIOCYANATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. |
| | | | The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%. |
| 448 | ALLYL PHENOXYACETATE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 449 | ALLYL TIGLATE | 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%. |
| 450 | ALMOND | Е | |
| 451 | ALMOND OIL | A, E, H | Amygdalin and hydrocyanic acid are mandatory components of Almond oil. The concentration of Amygdalin in the medicine must be 0%. The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |

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| | | | or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'. |
|-----|-------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 455 | ALOE PERRYI | А, Н | When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe perryi. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: (CHILD3) 'Use in children under 12 years is not recommended'; (LAX2) 'Prolonged use may cause serious bowel problems'; and (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, |

| 456 | | | 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 recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'. |
|-----|-----------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 456 | ALOE VERA | А, Е, Н | When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe vera. |

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

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| | | | 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'. |
|-----|------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 457 | ALOES CAPE | Α, Η | When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloes cape. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: (CHILD3) 'Use in children under 12 years is not recommended'; (LAX2) 'Prolonged use may cause serious bowel problems'; and (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect]. When promoted or marketed as a laxative, the medicine label: (LAX1) 'Drink plenty of water' [or words to that effect]. |

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| | | | When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'. |
|------------|---------------------------------------------------------------------------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 450 | | A TT | |
| 458 459 | ALOYSIA CITRODORA ALPHA CASOZEPINE ENRICHED HYDROLYSED MILK PROTEIN | A, H 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.' |
| 460 | ALPHA LIPOIC ACID | А | |
| 461 | ALPHA-2,2,6-TETRAMETHYL- CYCLOHEXENEBUTANAL | Ε | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. |

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| | | | The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
|-----|--------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 462 | ALPHA-AMYL CINNAMALDEHYDE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 463 | ALPHA-AMYL CINNAMYL ALCOHOL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 464 | ALPHA-CEDRENE EPOXIDE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 465 | ALPHA-DAMASCONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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

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| | | | combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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-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%. |
| 472 | ALPHA-ISO-METHYL IONONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 473 | ALPHA-METHYL ANISALACETONE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 474 | ALPHA-METHYL BENZYL | Е | Permitted for use only in |

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| | ALCOHOL | | combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
|-----|--------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 475 | ALPHA-METHYL BUTYRALDEHYDE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 476 | ALPHA-METHYL BUTYRIC ACID | 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%. |
| 477 | ALPHA-METHYL CINNAMALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 478 | ALPHA-METHYL FURFURAL | 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 |

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| | | | medicine must be no more than 5%. |
|-----|---------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 479 | ALPHA-METHYL NAPHTHYL KETONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 480 | ALPHA-METHYLCINNAMYL ALCOHOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 481 | ALPHA-N-METHYL IONONE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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-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%. |
| 483 | ALPHA-PINENE | Е | Permitted for use only in |

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| | | | combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
|-----|---------------------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 484 | ALPHA-SINENSAL | 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%. |
| 485 | ALPHA-TERPINENE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 486 | ALPHA-TERPINEOL | 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%. |
| 487 | ALPINIA GALANGA | A, H | |
| 488 | ALPINIA HAINANENSIS | A, H | |

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| 489 | ALPINIA OFFICINARUM | A, H | |
|-----|--------------------------------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 490 | ALPINIA OXYPHYLLA | A, H | |
| 491 | ALSIDIUM HELMINTHOCHORTON | A, H | Iodine is a mandatory component of Alsidium helminthochorton. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 492 | ALSTONIA BOONEI | A, H | |
| 493 | ALSTONIA CONSTRICTA | Н | Only for use as an active homoeopathic ingredient. |
| 494 | ALTERNANTHERA PHILOXEROIDES | А, Н | |
| 495 | ALTEROMONAS FERMENT EXTRACT | Ε | 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%. |
| 496 | ALTHAEA OFFICINALIS | А, Е, Н | |
| 497 | ALUM DODECAHYDRATE | А, Е, Н | |
| 498 | ALUMINIUM CHLOROHYDRATE | Ε | Only for use in topical medicines for dermal application. |
| 499 | ALUMINIUM CITRATE | E | Only for use in topical medicines for dermal application. |
| 500 | ALUMINIUM DISTEARATE | Е | Only for use in topical medicines for dermal application. |
| 501 | ALUMINIUM HYDROXIDE | E | Only for use in topical medicines for dermal application. |

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| 502 | ALUMINIUM HYDROXIDE HYDRATE | E | Only for use in topical medicines for dermal application. |
|-----|--------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 503 | ALUMINIUM MAGNESIUM SILICATE | Е | |
| 504 | ALUMINIUM MONOSTEARATE | E | Only for use in topical medicines for dermal application. |
| 505 | ALUMINIUM OXIDE | E, H | When used as an excipient ingredient, only for use in topical medicines for dermal application. When used as an active ingredient, only for use in homoeopathic medicines. |
| 506 | ALUMINIUM SILICATE | E, H | Only for use as an active homoeopathic or excipient ingredient. When used as an excipient ingredient, the medicine is only for use in topical medicines for dermal application. |
| 507 | ALUMINIUM SODIUM SILICATE | E | When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' |
| 508 | ALUMINIUM STARCH OCTENYLSUCCINATE | Е | The concentration in the medicine must be no more than 7%. |
| 509 | ALUMINIUM STEARATE | Е | Only for use in topical medicines for dermal application. |

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| 510 | ALUMINIUM SULFATE HYDRATE | 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%. |
| 511 | AMARANTH | Е | Permitted for use only as a colour for oral and topical use. |
| | | | ····· |
| 512 | AMARANTH ALUMINIUM LAKE | Е | Permitted for use only as a |
| | | | colour for oral and topical use |
| 513 | AMARANTHUS HYBRIDUS | А, Н | |
| 514 | AMARANTHUS RETROFLEXUS | A, H | |
| 515 | AMBERGRIS EXTRACT | Ε | Permitted for use only in |
| | | | combination with other |
| | | | permitted ingredients as a fragrance. |
| | | | The total fragrance |
| | | | concentration in a medicine |
| | | | must be no more than 1%. |
| 516 | AMBRETTE SEED OIL | 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%. |
| 517 | AMBRETTOLIDE | E | Permitted for use only in |
| | | | combination with other |
| | | | permitted ingredients as a |
| | | | flavour or a fragrance. |
| | | | If used in a flavour the total flavour concentration in a |
| | | | medicine must be no more |
| | | | than 5%. |
| | | | If used in a fragrance the total |
| | | | fragrance concentration in a |
| | | | medicine must be no more |
| | | | 1%. |
| 518 | AMBRINOL | Е | Permitted for use only in |

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| combination with other |
|----------------------------------|
| permitted ingredients as a |
| fragrance. |
| If used in a fragrance the total |
| fragrance concentration in a |
| medicine must be no more |
| than 1%. |

| 519 | AMBROSIA ARTEMISIIFOLIA | A, H | |
|-----|-----------------------------------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 520 | AMBROSIA PSILOSTACHYA | A, H | |
| 521 | AMINOBENZOIC ACID | A | Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%. |
| 522 | AMINOCAPROIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 523 | AMINOPROPYL ASCORBYL PHOSPHATE | 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 0.1%. |
| 524 | AMMI VISNAGA | А, Н | The concentration of equivalent dry Ammi visnaga in the product must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 525 | AMMONIA | E, H | Only for use as an active homoeopathic or excipient ingredient. When used as an excipient |

| | | | ingredient, the medicine is only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%. |
|-----|------------------------------------------------------------------------------|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 526 | AMMONIO METHACRYLATE COPOLYMER | Е | Only for use in oral medicines. |
| 527 | AMMONIUM ACRYLATES COPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 528 | AMMONIUM ACRYLATES/ACRYLONITROGENS COPOLYMER | Е | Only for use in topical medicines for dermal application. |
| 529 | AMMONIUM ACRYLOYLDIMETHYLTAURATE/S TEARETH-8 METHACRYLATE COPOLYMER | Ε | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%. |
| 530 | AMMONIUM ACRYLOYLDIMETHYLTAURATE/V P 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%. |
| 531 | AMMONIUM BICARBONATE | A, H | When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. |
| 532 | AMMONIUM BROMIDE | Н | Only for use as an active |

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| | | | homoeopathic ingredient. |
|-----|--------------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 533 | AMMONIUM CARBONATE | Е, Н | Only for use as an active homoeopathic or excipient ingredient. |
| 534 | AMMONIUM CHLORIDE | A, E, H | Only for use as an active ingredient in homoeopathic medicines or as an uncompounded medicine substance packed for retail sale. When used as an uncompounded medicine substance the ingredient must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. If used as an excipient ingredient then the medicine i only for topical use for derma application. |
| 535 | AMMONIUM GLYCYRRHIZINATE | Е | |
| 536 | AMMONIUM IODIDE | Н | Only for use an active ingredient in homoeopathic medicines. |
| 537 | AMMONIUM LACTATE | Ε | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%. |
| 538 | AMMONIUM LAURETH SULFATE | E | Only for use in topical medicines for dermal application. |
| 539 | AMMONIUM LAURYL SULFATE | E | Only for use in topical medicines for dermal application. |
| 540 | AMMONIUM POLYACRYLATE | E | Only for use in topical medicines for dermal application and not to be |

| | | | included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%. |
|-----|---------------------------------------------|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 541 | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 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 must be no more than 3%. |
| 542 | AMMONIUM SULFIDE | 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%. |
| 543 | AMOMUM AROMATICUM | A, H | |
| 544 | AMOMUM VILLOSUM | A, H | |
| 545 | AMORPHOPHALLUS KONJAC | A, H | Only for use when the dosage form is not tablet. |
| 546 | AMPELODESMOS MAURITANICUS | A, H | |
| 547 | AMPELOPSIS JAPONICA | A, H | |
| 548 | AMYL ACETATE | Ε | Only for use in: - topical medicines for dermal application; or - combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%. |
| 549 | AMYL ALCOHOL | 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 |

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| | | | medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
|-----|----------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 550 | AMYL BENZOATE | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 551 | AMYL BUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 552 | AMYL CAPROATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 553 | AMYL CINNAMATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more |

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| | | | than 5%. |
|-----|-----------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 554 | AMYL CINNAMIC ALCOHOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 555 | AMYL FORMATE | 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%. |
| 556 | 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%. |
| 557 | AMYL ISOVALERATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 558 | AMYL OCTANOATE | Е | Permitted for use only in combination with other permitted ingredients as a |

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| | | | flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
|-----|---------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 559 | AMYL PHENYLACETATE | 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%. |
| 560 | AMYL 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%. |
| 561 | AMYL SALICYLATE | 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%. |
| 562 | AMYL VALERATE | 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%. |
| 563 | AMYL VINYL CARBINOL | 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%. |
|-----|-------------------------------------------|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 564 | AMYL VINYL CARBINYL ACETATE | ЕЕ | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 565 | 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. |
| 566 | AMYLCYCLOHEXYL ACETATE (MIXED ISOMERS) | 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%. |
| 567 | AMYLOPECTIN | 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 |

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| | | | medicine must be no more than 5%. |
|-----|----------------------------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 568 | AMYRIS BALSAMIFERA | A, H | |
| 569 | AMYRIS OIL WEST INDIAN | А, Е, Н | |
| 570 | ANACARDIUM OCCIDENTALE | A, H | |
| 571 | ANACYCLUS PYRETHRUM | A, H | |
| 572 | ANACYSTIS NIDULANS FERMENT | Ε | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0025%. |
| 573 | ANAESTHETIC ETHER | Н | Only for use as an active homoeopathic ingredient. |
| 574 | ANAGALLIS ARVENSIS | A, H | |
| 575 | 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 mg/L or 0.001% |
| 576 | ANANAS COMOSUS | А, Е, Н | |
| 577 | ANAPHALIS SINICA | A, H | |
| 578 | ANDROGRAPHIS PANICULATA | A, H | |
| 579 | ANEMARRHENA ASPHODELOIDES | А, Е, Н | |
| 580 | ANEMONE ALTAICA | A, H | |
| 581 | ANEMONE CHINENSIS | A, H | |
| 582 | ANEMONE HEPATICA | A, H | |
| 583 | ANEMONE PULSATILLA | A, H | |
| 584 | ANEMONE RADDEANA | A, H | |
| 585 | ANETHOLE | Е | |
| 586 | ANETHOLEA ANISATA | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more |
| | | | than 5%. |

| 588 | ANGELICA ACUTILOBA | A, H | |
|-----|-----------------------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 589 | ANGELICA ANOMALA | A, H | |
| 590 | ANGELICA ARCHANGELICA | A, E, H | |
| 591 | ANGELICA ATROPURPUREA | A, H | |
| 592 | ANGELICA DAHURICA | A, E, H | |
| 593 | ANGELICA DECURSIVA | A, H | |
| 594 | ANGELICA POLYMORPHA | A, E, H | |
| 595 | ANGELICA PUBESCENS | A, E, H | |
| 596 | ANGELICA ROOT DRY | A, H | |
| 597 | ANGELICA ROOT OIL | A, E, H | |
| 598 | ANGELICA SEED OIL | A, E, H | |
| 599 | ANGELICA STEM | Е | |
| 600 | ANIBA ROSAEODORA | A, E, H | |
| | | | combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 602 | ANISE ALCOHOL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%. |
| 603 | ANISE OIL | A, E, H | When the concentration of Anise oil in the preparation is more than 50% the nominal capacity of the container mus 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 |

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| | | | container is 50 mL or less, a restricted flow insert must be fitted on the container. The medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children (or word to that effect)' |
|-----|----------------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 604 | ANISEED | 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 than 1%. |
| 605 | ANISEED DRY | A, E, H | |
| 606 | ANISEED POWDER | A, E, H | |
| 607 | ANISIC ACID | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 608 | ANISYL ACETATE | Ε | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 609 | ANISYL ACETONE | 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%. |
|-----|-----------------------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 610 | ANISYL FORMATE | 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%. |
| 611 | ANISYL PROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 612 | ANNATTO | Е | Permitted for use only as a colour for oral and topical use. |
| 613 | ANOGEISSUS LATIFOLIA | А, Е, Н | |
| 614 | ANTENNARIA DIOICA | А, Е, Н | |
| 615 | ANTHOCYANINS | Е | |
| 616 | ANTHOXANTHUM ODORATUM | А, Н | 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%. |
| | | A 11 | |
| 617 | ANTHRISCUS CEREFOLIUM | A, H | |

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| 619 | ANTIMONY POTASSIUM TARTRATE TRIHYDRATE | Н | Only for use as an active |
|-----|-------------------------------------------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | TAKTKATE TKIHYDKATE | | homoeopathic ingredient. |
| 620 | ANTIMONY TRISULFIDE | Н | Only for use as an active homoeopathic ingredient. |
| 621 | APIUM GRAVEOLENS | A, E, H | |
| 622 | APOCYNUM CANNABINUM | А, Н | The concentration of equivalent dry Apocynum cannabinum in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 623 | APOMORPHINE HYDROCHLORIDE HEMIHYDRATE | Н | Only for use as an active homoeopathic ingredient. |
| 624 | APPLE | Е | |
| 625 | APPLE CIDER VINEGAR | Е | |
| 626 | APPLE ESSENCE NATURAL | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 627 | APPLE EXTRACT | Ε | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 628 | APPLE FIBRE | Е | |
| 629 | APRICOT | Е | |
| 630 | APRICOT KERNEL OIL PEG-6 ESTERS | Е | Only for use as an excipient in topical medicines for dermal application. |
| 631 | AQUILARIA MALACCENSIS | A, H | |
| 632 | AQUILARIA SINENSIS | A, H | |
| 633 | AQUILEGIA VULGARIS | A, H | |
| 634 | ARACHIDONIC ACID | Е | Only for use in topical medicines for dermal |

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| | | | application. |
|-------------------|------------------------------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 635 | ARACHIDYL ALCOHOL | 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 1%. |
| 636 | ARACHIDYL GLUCOSIDE | 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 must be no more than 0.5%. |
| 637 | ARACHIDYL PROPIONATE | E | Only for use in topical medicines for dermal application. |
| 638 | ARACHIS HYPOGAEA | A, E, H | The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect). |
| 639 | ARACHIS OIL | Α, Ε, Η | The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect). |
| 640 | ARALIA CORDATA | A, H | |
| 641 | ARALIA HISPIDA | A, H | |
| 642 | ARALIA NUDICAULIS | A, H | |
| 643 | ARALIA RACEMOSA | A, H | |
| 644 | ARCTIUM LAPPA | A, E, H | |
| <u>645</u> 646 | ARCTIUM MINUS ARCTOSTAPHYLOS UVA-URSI | <u>A, H</u> A, E, H | Arbutin is a mandatory component of Arctostaphylos uva-ursi. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg |

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| | | | /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %. |
|-----|----------------------------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 647 | ARDISIA JAPONICA | A, H | |
| 648 | ARECA CATECHU | A, H | Arecoline is a mandatory component of Areca catechu. The concentration of arecoline in the medicine must be no more than 10 mg/Kg or 10 mg/L or 0.001%. |
| 649 | ARGANIA SPINOSA KERNEL OIL | Ε | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 5% in the medicine. |
| 650 | ARGININE | A, E, H | Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (ARGIN1) 'This medicine contains arginine and is intended to be applied to the skin only and not to the mucosa - vagina or rectum.' |
| 651 | ARGININE FERULATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%. |
| 652 | ARISAEMA ATRORUBENS | А, Н | The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material. |

| 653 | ARISAEMA CONSANGUINEUM | А, Н | The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
|-----|------------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 654 | ARISAEMA JAPONICUM | А, Н | The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 655 | ARMORACIA RUSTICANA | А, Е, Н | 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). |
| 656 | ARNEBIA EUCHROMA | A, H | |
| 657 | ARNICA FLOWER DRY | А, Н | 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. |
| 658 | ARNICA MOLLIS | А, Н | When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 659 | ARNICA MONTANA | А, Н | 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. |
| 660 | ARRHENATHERUM ELATIUS | A, H | |
| 661 | ARROWROOT | A, E, H | |
| 662 | ARSENIC TRIIODIDE | H | Only for use as an active homoeopathic ingredient. The concentration of arsenic in the |

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| | | | medicine must be no more than 0.001%. |
|-----|-----------------------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 663 | ARSENIC TRIOXIDE | Н | Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than 0.001%. |
| 664 | ARTEMISIA ABROTANUM | A, H | Thujone is a mandatory component of Artemisia abrotanum. The concentration of thujone from Artemisia abrotanum in the medicine must be no more than 4%. |
| 665 | ARTEMISIA ABSINTHIUM | А, Н | Thujone is a mandatory component of Artemisia absinthium. The concentration of thujone from Artemisia absinthium in the medicine must be no more than 4%. |
| 666 | ARTEMISIA ANNUA | А, Н | Thujone is a mandatory component of Artemisia annua. The concentration of thujone from Artemisia annua in the medicine must be no more than 4%. |
| 667 | ARTEMISIA ARBORESCENS | А, Н | Thujone is a mandatory component of Artemisia arborescens. The concentration of thujone from Artemisia arborescens in the medicine must be no more than 4%. |
| 668 | ARTEMISIA ARGYI | А, Н | Thujone is a mandatory component of Artemisia argyi The concentration of thujone from Artemisia argyi in the medicine must be no more than 4%. |
| 669 | ARTEMISIA DRACUNCULUS | A, E, H | Thujone is a mandatory |

| | | | component of Artemisia dracunculus. The concentration of thujone from Artemisia dracunculus in the medicine must be no more than 4%. |
|-----|----------------------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 670 | ARTEMISIA FRIGIDA | А, Н | Thujone is a mandatory component of Artemisia frigida. The concentration of thujone from Artemisia frigida in the medicine must be no more than 4%. |
| 671 | ARTEMISIA HERBA-ALBA | А, Н | Thujone is a mandatory component of Artemisia herba-alba. The concentration of thujone from Artemisia herba-alba in the medicine must be no more than 4%. |
| 672 | ARTEMISIA MARITIMA | А, Н | Thujone is a mandatory component of Artemisia maritima. The concentration of thujone from Artemisia maritima in the medicine must be no more than 4%. |
| 673 | ARTEMISIA OIL | 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%. |
| 674 | ARTEMISIA PALLENS | A, E, H | Thujone is a mandatory component of Artemisia pallens. The concentration of thujone |

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| | | | from Artemisia pallens in the medicine must be no more than 4%. |
|-----|------------------------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 675 | ARTEMISIA TRIDENTATA | А, Н | Thujone is a mandatory component of Artemisia tridentata. The concentration of thujone from Artemisia tridentata in the medicine must be no more than 4%. |
| 676 | ARTEMISIA VULGARIS | А, Е, Н | Thujone is a mandatory component of Artemisia vulgaris. The concentration of thujone from Artemisia vulgaris in the medicine must be no more than 4%. |
| 677 | ARTERY | Н | Only for use as an active homoeopathic ingredient. |
| 678 | ARTHROSPIRA MAXIMA | А, Е, Н | |
| 679 | ARTHROSPIRA PLATENSIS | А, Е, Н | |
| 680 | ARUM MACULATUM | А, Н | The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 681 | ASAFOETIDA GUM | A, H | |
| 682 | ASAFOETIDA OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 683 | ASARUM EUROPAEUM | A, H | |
| 684 | ASARUM HETEROTROPOIDES | A, H | |
| 685 | ASARUM OIL | E | |
| 686 | ASARUM SIEBOLDII | A, E, H | |
| 687 | ASCLEPIAS TUBEROSA | A, H | |
| 688 | ASCOPHYLLUM NODOSUM | A, E, H | Iodine is a mandatory component of Ascophyllum nodosum. Only for external use when the |

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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.

| 689 | ASCORBIC ACID | Α, Ε | |
|-----|-------------------------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 690 | ASCORBYL GLUCOSIDE | Ε | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. |
| 691 | ASCORBYL METHYLSILANOL PECTINATE | E | Only for use in topical medicines for dermal application. |
| 692 | ASCORBYL PALMITATE | Α, Ε | When for oral use, the maximum recommended daily dose must contain no more than 100mg of ascorbyl palmitate. |
| 693 | ASCORBYL TOCOPHERYL MALEATE | Е | 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%. |
| 694 | ASPALATHUS LINEARIS | А, Е, Н | |
| 695 | ASPARAGINE | A, E | |
| 696 | ASPARAGOPSIS SULFATED GALACTANS | Е | 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 |

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| | | | medicine must be no more than 0.0025%. |
|-----|-----------------------------------------------------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 697 | ASPARAGUS | Е, Н | Only for use as an active homoeopathic or excipient ingredient. |
| 698 | ASPARAGUS COCHINCHINENSIS | A, H | |
| 699 | ASPARAGUS OFFICINALIS | A, E, H | |
| 700 | ASPARAGUS RACEMOSUS | A, H | The plant part must be dried, peeled root, and water extracts or ethanol/water extracts (containing up to 45% ethanol) of the dried, peeled root. |
| 701 | ASPARTAME | E | When for oral use, the medicine requires the following warning statement on the medicine label: - (PKU) 'Phenylketonurics are warned that this product contains phenylalanine (or words to that effect)' The medicine requires the following warning statement on the medicine label: - (ASPAR) 'Contains aspartame' |
| 702 | ASPARTIC ACID | A, E | |
| 702 | ASPERGILLUS ORYZAE | A, E, H | |
| 704 | ASTAXANTHIN ESTERS EXTRACTED FROM HAEMATOCOCCUS PLUVIALIS | A | Only for use in oral medicines. Astaxanthin (of Haematococcus pluvialis) is a mandatory component of astaxanthin esters extracted from Haematococcus pluvialis. The maximum daily dose must contain no more than 12mg of Astaxanthin (of Haematococcus pluvialis). |
| 705 | ASTER NOVI-BELGII | A, H | |
| 706 | ASTER TATARICUS | A, H | |
| 707 | ASTRAGALUS ADSURGENS | A, H | |
| 708 | ASTRAGALUS COMPLANATUS | A, H | |

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| 709 | ASTRAGALUS EXCARPUS | A, H | |
|-----|--------------------------------------------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 710 | ASTRAGALUS GUMMIFER | A, E, H | |
| 711 | ASTRAGALUS LENTIGINOSUS | A, H | |
| 712 | ASTRAGALUS MEMBRANACEUS | А, Е, Н | |
| 713 | ASTRAGALUS PENDULIFLORUS | A, H | |
| 714 | ASTROCARYUM MURUMURU SEED TRIGLYCERIDES | Ε | Only for use as an ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.21%. |
| 715 | ATRACTYLODES JAPONICA | A, H | |
| 716 | ATRACTYLODES LANCEA | A, H | |
| 717 | ATRACTYLODES MACROCEPHALA | A, H | |
| 718 | ATROPA BELLADONNA | А, Н | 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%. |
| 719 | ATROPINE SULFATE MONOHYDRATE | Н | Only for use as an active homoeopathic ingredient. |
| 720 | ATTALEA SPECIOSA | Е | Only for use in topical medicines for dermal application. |
| 721 | AURA B-AURANTIOL | Ε | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 722 | AUREOBASIDIUM PULLULANS | A, H | |
|------------|-----------------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 723 | AVENA FATUA | А, Н | 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. |
| 724 | AVENA SATIVA | А, Е, Н | 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 to that effect. |
| 725 | AVOCADO | Б | |
| 725 726 | AVOCADO AVOCADO OIL | E E | |
| 727 | AVOCADO OIL UNSAPONIFIABLES | E | Only for use in topical medicines for dermal application. |
| 728 | 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 effect).' (NTAKEN) 'Not to be taken (or words to that effect).' (CHILD) 'Keep out of reach of children (or words to that effect).' |
|-----|-------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 729 | AZOVAN BLUE | E | Permitted for use only as a colour for topical use. |
| 730 | AZULENE | Е | Only for use in topical medicines for dermal application. |