



Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2022

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

Dated 12 January 2022

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

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Note: This instrument is in 6 volumes:

Volume 1:	Sections 1–7 (pages 2-4)
	Schedule 1 (+)-NARINGENIN–AZULENE (pages 5-135)
Volume 2:	Schedule 1 BACILLUS COAGULANS–EVERNIA PRUNASTRI EXTRACT (pages 136-377)
Volume 3:	Schedule 1 FABIANA IMBRICATA–JUSTICIA ADHATODA (pages 378-491)
Volume 4:	Schedule 1 KADSURA COCCINEA–OYSTER SHELL (pages 492-629)
Volume 5:	Schedule 1 P-ALPHA-DIMETHYL STYRENE–TYROSINE (pages 630-854)
Volume 6:	Schedule 1 UBIDECARENONE–ZUCCHINI (pages 855-885)

1 Name

This instrument is the *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2022*.

2 Commencement

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

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

Note: This table relates only to the provisions of this instrument as originally made.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

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

3 Authority

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

4 Interpretation

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

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

- (1) In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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

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

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

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

homoeopathic preparation has the same meaning as in the Regulations.

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

Regulations means the *Therapeutic Goods Regulations 1990*.

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

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

- (2) To avoid doubt, the terms set out in closed brackets in column 4 of the table in Schedule 1, which are associated with warning statements in relation to particular ingredients, are:
- (a) terms from the code tables under the heading *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 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, 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; and
- (b) the ingredient must comply with the requirements specified in relation to the ingredient in column 4 of that item; and
- (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

The *Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2021* is repealed.

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

Note: See sections 5 and 6.

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

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5	(5Z)-3-METHYL-5-CYCLOTETRADECEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
6	(E)-2-(3,5-DIMETHYLHEX-3-EN-2-YLOXY)-2-METHYLPROPYL CYCLOPROPANECARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
7	(E)-3-METHYLCYCLOPENTADEC-5-EN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
8	(E, E)-2,6-NONADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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%.
9	(R)-ALPHA-TERPINYL ACETATE	E	(R)-alpha-terpinyl acetate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.

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			The total concentration of the fragrance proprietary excipient formulation containing (R)-alpha-terpinyl acetate must not be more than 1% of the total medicine.
10	(S)-LACTIC ACID	A, E, H	
11	(S)-S-ADENOSYLMETHIONINE DISULFATE DITOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
12	(S)-S-ADENOSYLMETHIONINE DISULFATE TOSYLATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tosylate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
13	(S)-S-ADENOSYLMETHIONINE DISULFATE TRITOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine

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			disulfate tritosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
14	(S)-S-ADENOSYLMETHIONINE HEXASULFATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine hexasulfate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
15	(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

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			bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
16	(S)-S-ADENOSYLMETHIONINE PENTASULFATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine pentasulfate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: -(SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
17	(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)'
18	(S)-S-ADENOSYLMETHIONINE TETRASULFATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine tetrasulfate dihydrate. (S)-S-Adenosylmethionine in

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			the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
19	(S)-S-ADENOSYLMETHIONINE 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)'
20	(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

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			effect)
21	(Z)-HEX-3-ENYL 2-ETHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
22	(Z, Z)-3,6-NONADIEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
23	1,2,3,4,4A,5,8,8A-OCTAHYDRO-2,2,6,8-TETRAMETHYL-1-NAPHTHALENOL	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
24	1,2-HEXANEDIOL	E	Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye. The concentration in the medicine must be no more than 1%.
25	1,3,4,6,7,8A-HEXAHYDRO-1,1,5,5-TETRAMETHYL-2H-2,4A-METHANONAPHTHALEN-8(5H)-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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			fragrance concentration in a medicine must be no more than 1%.
26	1,3,5-UNDECATRIENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
27	1,3-BUTYLENE GLYCOL	E	
28	1,3-NONANEDIOL ACETATE, MIXED ESTERS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
29	1,3-NONANEDIOL, DIACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
30	1,4-CINEOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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

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36	1-(3,3-DIMETHYLCYCLOHEXYL)ETHYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
37	1-(4-ISOPROPYLCYCLOHEXYL)ETHANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
38	1-(5,5-DIMETHYL-1-CYCLOHEXEN-1-YL)-4-PENTEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
39	1-DODECANOL	E	Permitted for use: (a) only in combination with other permitted ingredients as a flavour; and (b) in topical medicines for dermal application. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
40	1-HEPTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
41	1-HEXEN-3-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
42	1-METHOXY-4-PROPENYLBENZENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
43	1-METHYL-2-[(1,2,2-TRIMETHYLBICYCLO[3.1.0]HEX-3-YL)METHYL]-CYCLOPROPANEMETHANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
44	1-METHYL-3-(2-METHYLPROPYL)-CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
45	1-METHYL-4-(4-METHYL-3-PENTENYL)-3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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				than 1%.
46	1-OCTEN-3-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
47	1-P-MENTHENE-8-THIOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
48	1-PENTEN-3-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
49	10-UNDECEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
50	10-UNDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a	

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			medicine must be no more 1%.
51	16-HYDROXY-12- OXAHEXADECANOIC ACID, OMEGA-LACTONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
52	2'-FUCOSYLLACTOSE	A	Only to be used in a medicine where BASF Australia Ltd - Australia (Client ID 13479), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 March 2023. Only for oral use. The maximum recommended daily dose of the medicine must not provide more than: (a) 5 g of 2'-fucosyllactose to individuals aged 18 years and older; (b) 2 g of 2'-fucosyllactose to individuals aged between 4 to 17 years (inclusive); and (c) 1.2 g of 2'-fucosyllactose to individuals aged between 1 to 3 years (inclusive). Not permitted for use in children under the age of 12 months.
53	2,2'-METHYLENEBIS(4-METHYL-6- TERT-BUTYLPHENOL)	E	2,2'-methylenebis(4-methyl-6- tert-butylphenol) must only be included in medicines when in combination with other permitted ingredients as a

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			proprietary excipient formulation in medicines with a dermal route of administration for topical application.
54	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%.
55	2,2,5-TRIMETHYL-5-PENTYLCYCLOPENTANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
56	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%.
57	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%.
58	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

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			flavour concentration in a medicine must be no more than 5%.
59	2,2-DIMETHYL-P-ETHYLPHENYL-PROPANENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
60	2,3,4-TRIMETHYL-3-PENTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
61	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%.
62	2,3,5-TRIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
63	2,3-DIETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.

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64	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%.
65	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%.
66	2,3-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
67	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%.
68	2,3-HEXANEDIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
69	2,3-PENTANEDIONE	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
70	2,4,5-TRIMETHYLTHIAZOLE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
71	2,4,6-TRIMETHYL-4-PHENYL-1,3-DIOXANE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
72	2,4-DECADIENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.</p> <p>The maximum daily dose must provide no more than 3 mg of 2,4-Decadienal.</p>
73	2,4-DIMETHYL BUTADIENEACROLEIN	E	<p>Permitted for use only in combination with other</p>

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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%.
74	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%.
75	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%.
76	2,4-DIMETHYL-4,4A,5,9B-TETRAHYDROINDENO[1,2-D]-1,3-DIOXIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
77	2,4-DIMETHYL-4-PHENYL TETRAHYDROFURAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
78	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

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			<p>flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.</p> <p>The maximum daily dose must provide no more than 3 mg of 2,4-Heptadienal.</p>
79	2,4-HEXADIENOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.</p> <p>The maximum daily dose must provide no more than 13.5 mg of 2,4-Hexadienol.</p>
80	2,5-DIETHYLTETRAHYDROFURAN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
81	2,5-DIMETHYL-2-OCTEN-6-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
82	2,5-DIMETHYL-4-ETHOXY-3(2H)-FURANONE	E	<p>Only for use in medicines in combination with other permitted ingredients as a</p>

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			flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
83	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%.
84	2,5-DIMETHYL-4-METHOXY-3(2H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
85	2,5-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance, or a printing ink. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
86	2,6,6-TRIMETHYL-2-	E	Permitted for use only in

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	CYCLOHEXENE-1,4-DIONE		<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
87	2,6,9,10-TETRAMETHYL-1-OXASPIRO(4.5)DECA-3,6-DIENE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
88	2,6-DIMETHOXYPHENOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
89	2,6-DIMETHYL HEPTAN-2-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
90	2,6-DIMETHYL-2-HEPTENAL-(7)	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more 1%.
91	2,6-DIMETHYL-3,5-OCTADIEN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
92	2,6-DIMETHYL-4-HEPTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
93	2,6-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
94	2,6-NONADIEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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95	2,6-OCTADIENOIC ACID, 3,7-DIMETHYL-, METHYL ESTER, (2E)-	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
96	2-(1,1-DIMETHYLETHYL)-1,4-DIMETHOXY-BENZENE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
97	2-(2-(4-METHYL-3-CYCLOHEXEN-1-YL)PROPYL)CYCLOPENTANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
98	2-(2-METHYLPHENYL)ETHANOL	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>The ingredient is not to be included in medicines intended for use in the eye.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
99	2-(4-METHYLPHENOXY)-N-1H-PYRAZOL-3-YL-N-(2-THIENYLMETHYL)ACETAMIDE	E	<p>The route of administration of a medicine containing 2-(4-methylphenoxy)-n-1h-pyrazol-3-yl-n-(2-thienylmethyl)acetamide must be limited to dental.</p> <p>The total concentration of 2-(4-methylphenoxy)-N-1H-</p>

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			<p>pyrazol-3-yl-N-(2-thienylmethyl)acetamide in the medicine must not be more than 0.015%.</p> <p>2-(4-Methylphenoxy)-N-1H-pyrazol-3-yl-N-(2-thienylmethyl)acetamide must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation</p> <p>The total concentration of flavour proprietary excipient formulations containing 2-(4-methylphenoxy)-N-1H-pyrazol-3-yl-N-(2-thienylmethyl)acetamide must not be more than 5% of the total medicine.</p>
100	2-(6-METHYL-8-ISOPROPYL BICYCLO(2.2.2)OCT-5-ENE-2-YL-1,3-DIOXOLANE	E	<p>2-(6-methyl-8-isopropyl bicyclo(2.2.2)oct-5-ene-2-yl)-1,3-dioxolane must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing 2-(6-methyl-8-isopropyl bicyclo(2.2.2)oct-5-ene-2-yl)-1,3-dioxolane must not be more than 1% of the total medicine.</p>
101	2-[(3,7-DIMETHYL-6-OCTEN-1-YLIDENE)AMINO]BENZOIC ACID, METHYL ESTER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
102	2-[1-(3,3-DIMETHYLCYCLOHEXYL)ETHOXY]-2-METHYLPROPYL]	E	Permitted for use only in combination with other permitted ingredients as a

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	CYCLOPROPANECARBOXYLATE		fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
103	2-[1-(3,3-DIMETHYLCYCLOHEXYL)ETHOXY]-2-OXOETHYL PROPANOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
104	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%.
105	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%.
106	2-ACETYLPYRIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
107	2-AMINO-2-METHYL-1-PROPANOL	E	Only for use in topical medicines for dermal

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			application.
108	2-BENZYL-4,4,6-TRIMETHYL-1,3-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
109	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%.
110	2-BUTYL-4,4,6-TRIMETHYL-1,3-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
111	2-CYCLOHEXYLIDENE-2-OTOLYL-ACETONITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
112	2-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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113	2-DODECANOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
114	2-DODECENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
115	2-ETHOXY-4-(METHOXYMETHYL)-PHENOL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
116	2-ETHOXY-9-METHYLENE-2,6,6-TRIMETHYLBICYCLO[3.3.1]NONANE	E	<p>2-ethoxy-9-methylene-2,6,6-trimethylbicyclo[3.3.1]nonane must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing 2-ethoxy-9-methylene-2,6,6-</p>

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			trimethylbicyclo[3.3.1]nonane must not be more than 1% of the total medicine.
117	2-ETHOXYETHANOL	E	The residual solvent limit for 2-Ethoxyethanol is 1.6 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.016%.
118	2-ETHYL-1-HEXANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
119	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 than 1%.
120	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 than 1%.
121	2-ETHYL-3-METHYLPYRAZINE	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
122	2-ETHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-2-BUTEN-1-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
123	2-ETHYL-4-HYDROXY-5-METHYL-3(2H)-FURANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
124	2-ETHYL-4-METHYLTHIAZOLE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
125	2-ETHYL-ALPHA,ALPHA-DIMETHYL-BENZENEPROPANAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more than 1%.
126	2-ETHYL-N-METHYL-N-(3-METHYLPHENYL) BUTANAMIDE	E	<p>Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.</p>
127	2-ETHYLBUTYRIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
128	2-HEPTANOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
129	2-HEPTANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
130	2-HEPTYL CYCLOPENTANONE	E	Permitted for use only in combination with other permitted ingredients as a

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			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
131	2-HEXENYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
132	2-HYDROXYACETOPHENONE	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 1%.</p>
133	2-ISOBUTYL-3-METHOXYPIRAZINE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
134	2-ISOBUTYL-4-METHYLTetrahydro-2H-PYRAN-4-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
135	2-ISOPROPOXYETHYL	E	Permitted for use only in

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SALICYLATE			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
136	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 than 1%.
137	2-ISOPROPYLPHENOL	E	2-Isopropylphenol must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing 2-isopropylphenol must not be more than 5% of the total medicine.
138	2-MERCAPTOPROPIONIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
139	2-METHOXY-3-(1-METHYLPROPYL)PYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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			fragrance concentration in a medicine must be no more than 1%.
140	2-METHOXY-4-VINYLPHENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
141	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%.
142	2-METHYL-2-PENTENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
143	2-METHYL-2-VINYL-5-ISOPROPENYLTETRAHYDROFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
144	2-METHYL-3-(3,4-METHYLENEDIOXYPHENYL)PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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				If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
145	2-METHYL-3-(4-METHOXYPHENYL)PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.	If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
146	2-METHYL-3-[4-(2-METHYLPROPYL)PHENYL]PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.	If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
147	2-METHYL-3-BUTEN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour.	If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
148	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%.
149	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%.

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			than 1%.
150	2-METHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTENYL)-2-BUTEN-1-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> <p>Only for use in topical medicines for dermal application.</p>
151	2-METHYL-4-(2,2,3-TRIMETHYLCYCLOPENT-3-EN-1-YL)PENT-4-EN-1-OL	E	<p>2-Methyl-4-(2,2,3-trimethylcyclopent-3-en-1-yl)pent-4-en-1-ol must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing 2-methyl-4-(2,2,3-trimethylcyclopent-3-en-1-yl)pent-4-en-1-ol must not be more than 1% of the total medicine.</p>
152	2-METHYL-4-(2,6,6-TRIMETHYL-1-CYCLOHEXEN-1-YL)-2-BUTENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
153	2-METHYL-4-(CAMPHENYL-8)-CYCLOHEXANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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154	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%.
155	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%.
156	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%.
157	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%.
158	2-METHYLBUTYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
159	2-METHYLBUTYL PHENYLETHYL ETHER	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
160	2-METHYLBUTYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
161	2-METHYLDECANAL	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
162	2-METHYLHEXANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
163	2-METHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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164	2-METHYLTETRAHYDROFURAN-3-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
165	2-METHYLUNDECANAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
166	2-METHYLVALERIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
167	2-NONENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
168	2-NONENENITRILE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
169	2-OXOBUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
170	2-PENTADECANONE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
171	2-PENTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
172	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%.
173	2-PENTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

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			medicine must be no more than 5%.
174	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%.
175	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%.
176	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%.
177	2-PROPENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
178	2-SEC-BUTYL CYCLOHEXANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
179	2-TERT-BUTYLCYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
180	2-TERT-BUTYLCYCLOHEXYLOXY-2-BUTANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
181	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 than 1%.
182	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

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			flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
183	2-TRIDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
184	2-TRIDECENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
185	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%.
186	3'-SIALYLLACTOSE SODIUM	A	Only to be used in a medicine where Glycom A/S (Client ID 76983), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph

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			<p>ceases to be a requirement for this ingredient after 25 October 2023.</p> <p>Lactose and sodium are mandatory components of 3'-sialyllactose sodium.</p> <p>The route of administration for medicines that contain 3'-sialyllactose sodium must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(a) 0.2 g 3'-sialyllactose sodium in infants under 12 months;</p> <p>(b) 0.15 g 3'-sialyllactose sodium in children aged 12-35 months; or</p> <p>(c) 0.5 g 3'-sialyllactose sodium in individuals aged 3 years and older.</p>
187	3,3-DIMETHYL-5-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-4-PENTEN-2-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
188	3,3-DIMETHYLACRYLIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
189	3,4,4A,5,8,8A-HEXAHYDRO-3',7-DIMETHYLSPIRO-1,4-METHANONAPHALENE-2(1H),2'-OXIRANE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more</p>

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				than 1%.
190	3,4-DIMETHYL PHENYLACETALDEHYDE	E		<p>3,4-Dimethyl phenylacetaldehyde must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing 3,4-dimethyl phenylacetaldehyde must not be more than 1% of the total medicine.</p>
191	3,4-DIMETHYL-1,2- CYCLOPENTADIONE	E		<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
192	3,5,5-TRIMETHYL HEXANAL	E		<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
193	3,5,5-TRIMETHYLHEXYL ACETATE	E		<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
194	3,5,6,6-TETRAMETHYL-4- METHYLENEHEPTAN-2-ONE	E		<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
195	3,5-DIMETHOXYTOLUENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
196	3,5-DIMETHYL-3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
197	3,6-DIMETHYL-3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
198	3,7-DIMETHYL OCTANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
199	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

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			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
200	3,7-DIMETHYL-1-OCTEN-3-OL	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
201	3,7-DIMETHYL-2,6-NONADIENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
202	3,7-DIMETHYL-2,6-OCTADIENAL REACTION PRODUCTS WITH ETHANOL	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
203	3,7-DIMETHYL-7-METHOXYOCTAN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
204	3-(1-BUTENYL)-PYRIDINE	E	3-(1-Butenyl)-pyridine must only be included in medicines when in combination with other permitted ingredients as

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			<p>a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing 3-(1-butenyl)-pyridine must not be more than 1% of the total medicine.</p>
205	3-(3-ISOPROPYLPHENYL)BUTANAL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
206	3-(4-ETHYLPHENYL)-2,2-DIMETHYLPROPANAL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
207	3-(4-HYDROXYPHENYL)-1-(2,4,6-TRIHYDROXYPHENYL)-1-PROPANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
208	3-(4-TERT-BUTYLPHENYL)-PROPANAL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
209	3-(ISO-CAMPHYL-5)-CYCLOHEXANOL	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
210	3-(METHYLTHIO) PROPIONALDEHYDE	E	<p>3-(Methylthio) propionaldehyde must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing 3-(methylthio) propionaldehyde must not be more than 5% of the total medicine.</p>
211	3-(METHYLTHIO)-1-HEXYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
212	3-CARENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
213	3-DODECENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a</p>

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			medicine must be no more than 1%.
214	3-ETHYLPYRIDINE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
215	3-HEPTYLDIHYDRO-5-METHYL-2(3H)-FURANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
216	3-HEXANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
217	3-HEXEN-1-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
218	3-ISO-CAMPHYL-5-CYCLOHEXAN-1-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more than 1%.
219	3-METHYL THIOPROPIONALDEHYDE ETHANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
220	3-METHYL-2- (PENTYLOXY)CYCLOPENT-2-EN- 1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
221	3-METHYL-5-(2,2,3-TRIMETHYL-3- CYCLOPENTEN-1-YL)-4-PENTEN- 2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
222	3-METHYL-5-PHENYL PENT-2- ENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
223	3-METHYL-5-PHENYLPENTANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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224	3-METHYL-5-PHENYLPENTANENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
225	3-METHYL-5-PHENYLPENTANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
226	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%.
227	3-METHYLCYCLOPENTADECANON E	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
228	3-METHYLCYCLOPENTADECENON E	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
229	3-METHYLPENTANOIC ACID	E	3-Methylpentanoic acid must

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			<p>only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of the flavour proprietary excipient formulation containing 3-methylpentanoic acid must not be more than 5% of the total medicine.</p>
230	3-METHYLTHIOHEXANOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
231	3-OCTANOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
232	3-OCTYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
233	3-PENTYLTETRAHYDRO-2H-PYRAN-4-OL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
234	3-PHENYLPROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
235	3-PHENYLPROPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
236	3-PHENYLPROPYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
237	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
238	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%.
239	3A,6,6,9A- TETRAMETHYLDODECAHYDRON APHTHO[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%.
240	4,4A,5,9B-TETRAHYDRO-2,4- DIMETHYL-INDENO(1,2-D)-1,3- DIOXIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
241	4,4A,5,9B- TETRAHYDROINDENO(1,2-D)-1,3- DIOXIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
242	4,5-DIMETHYL-3-HYDROXY- 2(5H)FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 1%.

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			than 5%.
243	4,7-METHANO-1H-INDENEMETHANOL, OCTAHYDRO-, ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
244	4,7-METHANO-3A,4,5,6,7,7A-HEXAHYDRO-5 (OR 6) -INDENYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
245	4,8-DIMETHYL-3,7-NONADIEN-2-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
246	4-(1-ETHOXYVINYL)-3,3,5,5-TETRAMETHYLCYCLOHEXANON E	E	<p>4-(1-Ethoxyvinyl)-3,3,5,5-tetramethylcyclohexanone must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing 4-(1-ethoxyvinyl)-3,3,5,5-tetramethylcyclohexanone must not be more than 1% of the total medicine.</p>
247	4-(4-METHYL-3-PENTEN-1-YL)-3-	E	Permitted for use only in

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	CYCLOHEXENE-1-CARBOXALDEHYDE		<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
248	4-(5,5,6-TRIMETHYLBICYCLO(2.2.1)HEPT-2-YL)-CYCLOHEXANOL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
249	4-(METHYLTHIO)-4-METHYL-2-PENTANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
250	4-(OCTAHYDRO-4,7-METHANO-5H-INDEN-5-YLIDENE)-BUTANAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
251	4-(PARA-HYDROXYPHENYL)-2-BUTANONE	E	<p>4-(para-hydroxyphenyl)-2-butanone must only be included in medicines when:</p> <p>(a) in combination with other permitted ingredients as a flavour proprietary excipient formulation;</p> <p>(b) in combination with other permitted ingredients as a</p>

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			<p>fragrance proprietary excipient formulation; and/or (c) in topical medicines for dermal application that are not intended for use in the eye or on damaged skin.</p> <p>The total concentration of flavour proprietary excipient formulations containing 4-(para-hydroxyphenyl)-2-butanone must not be more than 5% of the total medicine.</p> <p>The total concentration of fragrance proprietary excipient formulations containing 4-(para-hydroxyphenyl)-2-butanone must not be more than 1% of the total medicine.</p> <p>The concentration of 4-(para-hydroxyphenyl)-2-butanone in a topical medicine for dermal application must not be more than 1% of the total medicine.</p>
252	4-(PARA-METHOXYPHENYL)-2-BUTANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
253	4-ACETYL-6-TERTIARY-BUTYL-1,1-DIMETHYLINDAN	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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254	4-CYCLOHEXYL-2-METHYL-2-BUTANOL	E	<p>Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.</p>
255	4-ETHYL GUAIACOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
256	4-HEPTANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
257	4-HYDROXYBENZALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
258	4-HYDROXYBENZYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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			than 5%.
259	4-ISOPROPYL-3-METHYLPHENOL	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
260	4-METHOXY-2-METHYL-2-BUTANETHIOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
261	4-METHYL-3-DECEN-5-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
262	4-METHYL-4-MERCAPTOPENTAN-2-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
263	4-METHYL-4-PHENYL-2-PENTYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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264	4-METHYL-5-THIAZOLETHANOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
265	4-METHYLBENZYLIDENE CAMPHOR	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 4%.</p> <p>The following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
266	4-METHYLPENTANOIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
267	4-METHYLPHENYL OCTANOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more</p>

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			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
268	4-PARA METHOXYPHENYL-3-BUTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
269	4-PENTENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
270	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%.
271	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%.
272	4-TERT-PENTYLCYCLOHEXANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
273	5,6,7,8-TETRAHYDROQUINOXALINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
274	5,7-DIHYDRO-2-METHYLTHIENO (3,4D) PYRIMIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
275	5-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-3-METHYLPENTAN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
276	5-ACETYL-1,1,2,3,3,6-HEXAMETHYL INDAN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
277	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

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			fragrance concentration in a medicine must be no more than 1%.
278	5-ETHYL-2,3-DIMETHYLPYRAZINE	E	<p>5-Ethyl-2,3,dimethylpyrazine must not be included in medicines for oral administration.</p> <p>5-Ethyl-2,3,dimethylpyrazine must only be included in topical medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing 5-ethyl-2,3,dimethylpyrazine must not be more than 1% of the total medicine.</p>
279	5-ETHYL-3-HYDOXY-4-METHYL-2(5H)-FURANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
280	5-ETHYL-4-HYDROXY-2-METHYL-3(2H)-FURANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
281	5-HYDROXY-4-METHYLHEXANOIC ACID DELTA-LACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more</p>

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				than 5%.
282	5-METHOXYPBORALEN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.	
283	5-METHYL 2-PHENYL HEXEN-2-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
284	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%.	
285	5-METHYL-3-BUTYL-TETRAHYDRO-PYRAN-4-YL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.	
286	5-METHYL-3-HEPTANONE OXIME	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.	
287	5-PENTYL-2(5H)-FURANONE	E	Permitted for use only in	

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			<p>combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
288	6'-SIALYLLACTOSE SODIUM	A	<p>Only to be used in a medicine where Glycom A/S (Client ID 76983), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 25 October 2023.</p> <p>Lactose and sodium are mandatory components of 6'-sialyllactose sodium.</p> <p>The route of administration for medicines that contain 6'-sialyllactose sodium must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(a) 0.4 g 6'-sialyllactose sodium in infants under 12 months;</p> <p>(b) 0.3 g 6'-sialyllactose sodium in children aged 12-35 months; or</p> <p>(c) 1.0 g 6'-sialyllactose sodium in individuals aged 3 years and older.</p>
289	6,6-DIMETHOXY-2,5,5-TRIMETHYL-2-HEXENE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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290	6,6-DIMETHYL-2-NORPINENEPROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
291	6,7-DIHYDRO-1,1,2,3,3-PENTAMETHYL-4(5H)-INDANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
292	6-BUTYL-3,6-DIHYDRO-2,4-DIMETHYL-2H-PYRAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
293	6-ETHYLIDENEOCTAHYDRO 5,8-METHANO-2H-1-BENZOPYRAN	E	6-Ethylideneoctahydro 5,8-methano-2H-1-benzopyran must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing 6-ethylideneoctahydro 5,8-methano-2H-1-benzopyran must not be more than 1% of the total medicine.
294	6-METHOXY-2,6-DIMETHYLHEPTAN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a

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			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
295	6-METHOXYDICYCLOPENTADIENE CARBOXALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>When included in a medicine for use on the lips the concentration of 6-methoxydicyclopentadiene carboxaldehyde must be no more than 0.1%.</p> <p>When included in dermal creams for infant use the concentration of 6-methoxydicyclopentadienecarboxaldehyde must be no more than 0.5%.</p> <p>When for dermal use or use on the hair the concentration of 6-methoxydicyclopentadienecarboxaldehyde must be no more than 0.5%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
296	6-METHYL COUMARIN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
297	6-METHYL-2-BUTEN-3-OL-2	E	
298	6-METHYLQUINOLINE	E	<p>6-Methylquinoline must only be included in medicines when in combination with other permitted ingredients as</p>

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			<p>a flavour proprietary excipient formulation.</p> <p>The total concentration of the flavour proprietary excipient formulation containing 6-methylquinoline must not be more than 5% of the total medicine.</p>
299	7-ACETYL-1,1,3,4,4,6-HEXAMETHYL TETRAHYDRONAPHTHALENE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
300	7-METHYL-2H-1,5-BENZODIOXEPIN-3(4H)-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
301	7-OCTENE-1,6-DIOL, 3,7-DIMETHYL-	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
302	7-PROPYL-2H-1,5-BENZODIOXEPIN-3(4H)-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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303	8,13:13,20-DIEPOXY-14,15-BISNORLABDANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
304	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%.
305	8-OCIMENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
306	9-DECEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
307	ABELMOSCHUS MOSCHATUS	A, H	
308	ABELMOSCHUS MOSCHATUS SUBSP. MOSCHATUS	A, H	
309	ABIES BALSAMEA	A, H	
310	ABIES NIGRA	A, H	
311	ABIES PECTINATA	A, H	
312	ABIES SIBIRICA	A, H	
313	ABRUS CANTONIENSIS	A, H	If the herbal substance is derived from the seed, the

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			maximum recommended daily dose of <i>Abrus cantoniensis</i> must be no more than 1mg of the dry seed.
314	ABUTILON THEOPHRASTI	A, H	
315	ACACIA	A, E, H	
316	ACACIA BAILEYANA	A, H	
317	ACACIA CATECHU	A, H	
318	ACACIA DEALBATA	A, H	
319	ACACIA DECURRENS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
320	ACACIA FARNESIANA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
321	ACACIA LONGIFOLIA	A, E, H	
322	ACACIA NILOTICA	A, E, H	
323	ACACIA SENEGAL	A, E, H	
324	ACALYPHA INDICA	A, H	
325	ACANTHUS MOLLIS	A, H	
326	ACER CAMPESTRE	A, H	
327	ACER NEGUNDO	A, H	
328	ACER SACCHARINUM	A, H	
329	ACER SACCHARUM	A, E, H	
330	ACEROLA	E	
331	ACESULFAME POTASSIUM	E	
332	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

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
333	ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
334	ACETALDEHYDE ETHYL LINALYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
335	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%.
336	ACETALDEHYDE PHENYLETHYL PROPYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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337	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%.
338	ACETIC ACID	E, H	The concentration in the medicine must be no more than 80%.
339	ACETOIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
340	ACETOMENAPHTHONE	A, E	
341	ACETONE	E	The residual solvent limit for Acetone is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
342	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
343	ACETOVANILLONE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
344	ACETOXYDIHYDRODICYCLOPEN TADIENE	E	<p>Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.</p>
345	ACETYL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
346	ACETYL DIPEPTIDE-1 CETYL ESTER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.01%.</p>
347	ACETYL GLUCOSAMINE	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
348	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%.
349	ACETYL LEVOCARNITINE HYDROCHLORIDE	A, E	
350	ACETYL TRIFLUOROMETHYLPHENYL VALYLGLYCINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
351	ACETYLATED LANOLIN	E	Only for use in topical medicines for dermal application.
352	ACETYLATED LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
353	ACETYLATED MONOGLYCERIDES	E	
354	ACETYLATED VETIVER OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
355	ACETYLCYSTEINE	E	Only for use in topical

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			medicines for dermal application. The concentration in the medicine must be no more than 0.001%.
356	ACHILLEA ERBA-ROTTA SUBSP. MOSCHATA	A, H	
357	ACHILLEA MILLEFOLIUM	A, E, H	Beta-arbutin is a mandatory component of Achillea millefolium. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
358	ACHILLEA PTARMICA	A, H	
359	ACHYRANTHES ASPERA	A, H	
360	ACHYRANTHES BIDENTATA	A, H	
361	ACHYRANTHES FAURIEI	A, H	
362	ACID GREEN 25	E	Permitted for use only as a colour for topical use.
363	ACID RED 33	E	Permitted for use only as a colour for topical use.
364	ACID RED 87	E, H	Only for use as an active homoeopathic ingredient or

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			for excipient use as a colour in topical medicines.
365	ACID TREATED WAXY MAIZE STARCH	E	
366	ACID-ISOMERISED LINALOOL	E	Permitted for use only when combined with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
367	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.
368	ACONITUM FEROX	A, H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum ferox. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
369	ACONITUM KUSNEZOFFII	A, H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum kusnezoffii. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
370	ACONITUM NAPELLUS	A, H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum napellus. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02

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			milligrams per pack.
371	ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.7%.
372	ACRYLAMIDES COPOLYMER	E	Only for use in topical medicines for dermal application.
373	ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
374	ACRYLATES/ACRYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application.
375	ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
376	ACRYLATES/C12-22 ALKYL METHACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
377	ACRYLATES/DIMETHICONE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
378	ACRYLATES/OCTYLACRYLAMID E COPOLYMER	E	Only for use in topical medicines for dermal

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			application.
379	ACRYLATES/STEARETH-20 METHACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
380	ACRYLATES/VA COPOLYMER	E	Only for use in topical medicines for dermal application.
381	ACRYLIC ACID/VP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
382	ACTAEA CIMICIFUGA	A, H	
383	ACTAEA HERACLEIFOLIA	A, H	
384	ACTAEA PACHYPODA	A, H	
385	ACTAEA RACEMOSA	A, H	When used in oral medicines, the medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
386	ACTAEA SIMPLEX	A, H	
387	ACTAEA SPICATA	A, H	
388	ACTINIDIA CHINENSIS	A, H	

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389	ACTINIDIA DELICIOSA	A, H	
390	ACTIVATED ATTAPULGITE	A	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
391	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).
392	ADEMETHIONINE DISULFATE DITOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate ditosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed 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)'
393	ADEMETHIONINE DISULFATE TOSYLATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate

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			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)'
394	ADEMETIONINE DISULFATE TRITOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tritosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine 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)'
395	ADEMETIONINE HEXASULFATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine hexasulfate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under

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

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

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401	ADEMETIONINE TRISULFATE DITOSYLATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine trisulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
402	ADENOPHORA STRICTA	A, H	
403	ADENOPHORA TRIPHYLLA	A, H	
404	ADENOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.04%.
405	ADENOSINE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
406	ADENOSINE TRIPHOSPHATE	E	Only for use in topical medicines for dermal application.
407	ADENOSINE TRIPHOSPHATE DISODIUM	E	Only for use in topical medicines for dermal application.

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408	ADIANTUM CAPILLUS-VENERIS	A, H	
409	ADIPIC ACID	E	
410	ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
411	ADONIS VERNALIS	A, H	The concentration of equivalent dry Adonis vernalis in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
412	ADRENALINE (EPINEPHRINE)	H	Only for use as an active homoeopathic ingredient.
413	ADZUKI BEAN	E	
414	AEGOPODIUM PODAGRARIA	A, H	
415	AESCULUS CHINENSIS	A, H	
416	AESCULUS GLABRA	A, H	
417	AESCULUS HIPPOCASTANUM	A, H	
418	AESCULUS X CARNEA	A, H	
419	AETHUSA CYNAPIUM	H	Only for use as an active homoeopathic ingredient.
420	AGAR	A, E	
421	AGASTACHE RUGOSA	A, H	
422	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%.
423	AGAVE AMERICANA	A, E, H	
424	AGRIMONIA EUPATORIA	A, E, H	
425	AGRIMONIA REPENS	A, H	
426	AGROSTIS TENUIS	A, H	
427	AILANTHUS ALTISSIMA	A, H	

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428	AJUGA CHAMAEPITYS	A, H	
429	AJUGA REPTANS	A, H	
430	ALANINE	A, E	
431	ALANYLGLUTAMINE	A	Only for use in oral medicines.
432	ALARIA ESCULENTA	A, H	Iodine is a mandatory component of Alaria esculenta. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
433	ALBIZIA JULIBRISSIN	A, H	
434	ALBIZIA LEBBECK	A, H	
435	ALCEA ROSEA	A, H	
436	ALCHEMILLA ALPINA	A, H	
437	ALCHEMILLA ARVENSIS	A, H	
438	ALCHEMILLA VULGARIS	A, H	
439	ALETRIS FARINOSA	A, H	
440	ALETRIS SPICATA	A, H	
441	ALEURITES MOLUCCANUS SEED OIL	E	Only for use in topical medicines for dermal application.
442	ALFADEX	A, E	Only for use in oral medicines. The maximum daily dose must provide no more than 6 g of alfadex.
443	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

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			than 13.5 g. 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).
444	ALGINIC ACID	E	
445	ALISMA ORIENTALE	A, H	
446	ALISMA PLANTAGO AQUATICA	A, H	
447	ALKANNA TINCTORIA	A, H	
448	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%.
449	ALLANTOIN	E	Only for use in topical medicines for dermal application.
450	ALLIARIA PETIOLATA	A, H	
451	ALLIUM CEPA	A, H	
452	ALLIUM FISTULOSUM	A, H	
453	ALLIUM HIEROCHUNTINUM	A, H	
454	ALLIUM MACROSTEMON	A, H	
455	ALLIUM ODORUM	A, H	
456	ALLIUM PORRUM	A, H	
457	ALLIUM SATIVUM	A, E, H	
458	ALLIUM SCHOENOPRASUM	A, H	
459	ALLIUM URSINUM	A, H	
460	ALLO-OCIMENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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461	ALLURA RED AC	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
462	ALLURA RED AC ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
463	ALLYL ALPHA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
464	ALLYL AMYL GLYCOLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
465	ALLYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
466	ALLYL CYCLOHEXANEPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
467	ALLYL CYCLOHEXYLOXYACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
468	ALLYL HEPTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
469	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%.
470	ALLYL HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more

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			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
471	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%.
472	ALLYL PHENOXYACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
473	ALLYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
474	ALMOND	E	
475	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

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			than 1 microgram/kg or 1 microgram/L or 0.000001%.
476	ALNUS GLUTINOSA	A, H	
477	ALNUS INCANA SUBSP. RUGOSA	A, H	
478	ALOE FEROX	A, E, H	<p>When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe ferox.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect]. <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' [or words to that effect]. <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p>

			<p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
479	ALOE PERRYI	A, H	<p>When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe perryi.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or</p>

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vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].

When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:

- (LAX1) 'Drink plenty of water' [or words to that effect].

When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and

- (LAX4) 'This product may have laxative effect'.

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

- (CHILD3) 'Use in children 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'.

480	ALOE VERA	A, E, H	When the route of administration is oral or sublingual, Hydroxyanthracene
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derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe vera.

When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:

- (CHILD3) 'Use in children under 12 years is not recommended';
- (LAX2) 'Prolonged use may cause serious bowel problems'; and
- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].

When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:

- (LAX1) 'Drink plenty of water' [or words to that effect].

When not promoted or marketed as laxative, the medicine requires the following warning statements 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

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			<p>10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
481	ALOES CAPE	A, H	<p>When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloes cape.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect]. <p>When promoted or marketed as a laxative, the medicine requires the following</p>

			<p>warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' [or words to that effect].</p> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
482	ALOYSIA CITRODORA	A, H	
483	ALPHA CASOZEPINE ENRICHED HYDROLYSED MILK PROTEIN	A	<p>Only for use in oral medicines.</p> <p>The following warning statement is required on the medicine label:</p> <p>- (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect).</p>

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484	ALPHA LIPOIC ACID	A	
485	ALPHA-2,2,6-TETRAMETHYL-CYCLOHEXENEBUTANAL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
486	ALPHA-AMYL CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
487	ALPHA-AMYL CINNAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
488	ALPHA-CEDRENE EPOXIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
489	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

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
490	ALPHA-FARNESENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
491	ALPHA-FURFURYL OCTANOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
492	ALPHA- HEXYLCINNAMALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
493	ALPHA-IONOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a</p>

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

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			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
498	ALPHA-METHYL BENZYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
499	ALPHA-METHYL BUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
500	ALPHA-METHYL BUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
501	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

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			medicine must be no more 1%.
502	ALPHA-METHYL FURFURAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
503	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%.
504	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%.
505	ALPHA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
506	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

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			<p>flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
507	ALPHA-PINENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
508	ALPHA-SANTALOL	E	<p>alpha-Santalol must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing alpha-santalol must not be more than 1% of the total medicine.</p>
509	ALPHA-SINENSAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
510	ALPHA-TERPINENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
511	ALPHA-TERPINEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
512	ALPINIA GALANGA	A, H	
513	ALPINIA HAINANENSIS	A, H	
514	ALPINIA OFFICINARUM	A, H	
515	ALPINIA OXYPHYLLA	A, H	
516	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.
517	ALSTONIA BOONEI	A, H	
518	ALSTONIA CONSTRICTA	H	Only for use as an active homoeopathic ingredient.
519	ALTERNANTHERA PHILOXEROIDES	A, H	
520	ALTEROMONAS FERMENT EXTRACT	E	Only for use in topical medicines for dermal

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			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%.
521	ALTHAEA OFFICINALIS	A, E, H	
522	ALUM DODECAHYDRATE	A, E, H	
523	ALUMINIUM CHLOROHYDRATE	E	Only for use in topical medicines for dermal application.
524	ALUMINIUM CITRATE	E	Only for use in topical medicines for dermal application.
525	ALUMINIUM DISTEARATE	E	Only for use in topical medicines for dermal application.
526	ALUMINIUM HYDROXIDE	E	Only for use in topical medicines for dermal application.
527	ALUMINIUM HYDROXIDE HYDRATE	E	Only for use in topical medicines for dermal application.
528	ALUMINIUM MAGNESIUM SILICATE	E	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1 March 2022. (a) Magnesium is a mandatory component of aluminium magnesium silicate. (b) When used in a medicine: (i) with an oral route of administration; (ii) not indicated for laxative (or related) use; and

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			<p>(iii) where the maximum recommended daily dose for:</p> <p>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
529	ALUMINIUM MONOSTEARATE	E	Only for use in topical medicines for dermal application.
530	ALUMINIUM OXIDE	E, H	<p>When used as an excipient ingredient, only for use in topical medicines for dermal application.</p> <p>When used as an active ingredient, only for use in homoeopathic medicines.</p>
531	ALUMINIUM SILICATE	E, H	<p>Only for use as an active homoeopathic or excipient ingredient.</p> <p>When used as an excipient ingredient, the medicine is only for use in topical</p>

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			medicines for dermal application.
532	ALUMINIUM SODIUM SILICATE	E	
533	ALUMINIUM STARCH OCTENYLSUCCINATE	E	The concentration in the medicine must be no more than 7%.
534	ALUMINIUM STEARATE	E	Only for use in topical medicines for dermal application.
535	ALUMINIUM SULFATE HYDRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
536	AMARANTH	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
537	AMARANTH ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use
538	AMARANTHUS HYBRIDUS	A, H	
539	AMARANTHUS RETROFLEXUS	A, H	
540	AMBERGRIS EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a fragrance. The total fragrance concentration in a medicine must be no more than 1%.
541	AMBRETTE SEED OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more

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			than 5%.
542	AMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
543	AMBRINOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
544	AMBROSIA ARTEMISIIFOLIA	A, H	
545	AMBROSIA PSILOSTACHYA	A, H	
546	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%.
547	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%.
548	AMINOPROPYL ASCORBYL	E	Only for use in topical

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	PHOSPHATE		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%.
549	AMMI VISNAGA	A, H	The concentration of equivalent dry Ammi visnaga in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
550	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%.
551	AMMONIO METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
552	AMMONIUM ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
553	AMMONIUM ACRYLATES/ACRYLONITROGENS COPOLYMER	E	Only for use in topical medicines for dermal application.
554	AMMONIUM ACRYLOYLDIMETHYLTAURATE/ STEARETH-8 METHACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
555	AMMONIUM	E	Only for use in topical

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	ACRYLOYLDIMETHYLTAURATE/ VP COPOLYMER		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%.
556	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.
557	AMMONIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
558	AMMONIUM CARBONATE	E, H	Only for use as an active homoeopathic or excipient ingredient.
559	AMMONIUM CHLORIDE	A, E, H	Only for use as an active ingredient in homoeopathic medicines or as an uncompounded medicine substance packed for retail sale. When used as an uncompounded medicine substance the ingredient must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. If used as an excipient ingredient then the medicine is only for topical use for dermal application.
560	AMMONIUM GLYCYRRHIZINATE	E	
561	AMMONIUM IODIDE	H	Only for use an active ingredient in homoeopathic medicines.

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562	AMMONIUM LACTATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
563	AMMONIUM LAURETH SULFATE	E	Only for use in topical medicines for dermal application.
564	AMMONIUM LAURYL SULFATE	E	Only for use in topical medicines for dermal application.
565	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%.
566	AMMONIUM POLYACRYLOYLDIMETHYL TAURATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 3%.
567	AMMONIUM SULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
568	AMOMUM AROMATICUM	A, H	
569	AMOMUM VILLOSUM	A, H	

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570	AMORPHOPHALLUS KONJAC	A, H	Only for use when the dosage form is not tablet.
571	AMPELODES MOS MAURITANICUS	A, H	
572	AMPELOPSIS JAPONICA	A, H	
573	AMYL ACETATE	E	Only for use in: - topical medicines for dermal application; or - combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
574	AMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
575	AMYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
576	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

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			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
577	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 than 1%.
578	AMYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
579	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%.
580	AMYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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			1%.
581	AMYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
582	AMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
583	AMYL OCTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
584	AMYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
585	AMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

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			medicine must be no more than 5%.
586	AMYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
587	AMYL VALERATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
588	AMYL VINYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
589	AMYL VINYL CARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
590	AMYLASE	A	Amylase must be derived

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			from <i>Aspergillus oryzae</i> , and comply with the relevant compositional guideline.
591	AMYL CYCLOHEXYL ACETATE (MIXED ISOMERS)	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
592	AMYLOPECTIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
593	AMYRIS BALSAMIFERA	A, H	
594	AMYRIS OIL WEST INDIAN	A, E, H	
595	ANACARDIUM OCCIDENTALE	A, H	
596	ANACYCLUS PYRETHRUM	A, H	
597	ANACYSTIS NIDULANS FERMENT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0025%.
598	ANAESTHETIC ETHER	H	Only for use as an active homeopathic ingredient.
599	ANAGALLIS ARVENSIS	A, H	
600	ANAMIRTA COCCULUS	A, H	Picrotoxin is a mandatory component of <i>Anamirta cocculus</i> . The concentration of picrotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.

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601	ANANAS COMOSUS	A, E, H	
602	ANAPHALIS SINICA	A, H	
603	ANDROGRAPHIS PANICULATA	A, H	<p>The following warning statement is required on the label:</p> <p>- (ANDROG) ‘Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention’ (or words to that effect).</p> <p>The requirement specified in paragraph (a) below applies to medicines that contain the ingredient that are:</p> <p>- listed in the Register on or after 1 March 2021; or</p> <p>- released for supply after 1 March 2022.</p> <p>(a) When for oral use, the following warning statement is required on the medicine label:</p> <p>- (ANDROT) ‘Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical advice’ (or words to that effect).</p>
604	ANEMARRHENA ASPHODELOIDES	A, E, H	
605	ANEMONE ALTAICA	A, H	
606	ANEMONE CHINENSIS	A, H	
607	ANEMONE HEPATICA	A, H	
608	ANEMONE PULSATILLA	A, H	
609	ANEMONE RADDEANA	A, H	
610	ANETHOLE	E	
611	ANETHOLEA ANISATA	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%.
612	ANETHUM GRAVEOLENS	A, E, H	
613	ANGELICA ACUTILOBA	A, H	
614	ANGELICA ANOMALA	A, H	
615	ANGELICA ARCHANGELICA	A, E, H	
616	ANGELICA ATROPURPUREA	A, H	
617	ANGELICA DAHURICA	A, E, H	
618	ANGELICA DECURSIVA	A, H	
619	ANGELICA POLYMORPHA	A, E, H	
620	ANGELICA PUBESCENS	A, E, H	
621	ANGELICA ROOT DRY	A, H	
622	ANGELICA ROOT OIL	A, E, H	
623	ANGELICA SEED OIL	A, E, H	
624	ANGELICA STEM	E	
625	ANIBA ROSAEODORA	A, E, H	
626	ANISALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
627	ANISE ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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628	ANISE OIL	A, E, H	<p>When the concentration of Anise oil in the preparation is more than 50% the nominal capacity of the container must be no more than 50 mL.</p> <p>When the concentration of Anise oil in the preparation is more than 50% and the nominal capacity of the container is 50 mL or less, a restricted flow insert must be fitted on the container.</p> <p>The medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children (or word to that effect)'</p>
629	ANISEED	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
630	ANISEED DRY	A, E, H	
631	ANISEED POWDER	A, E, H	
632	ANISIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
633	ANISYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
634	ANISYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
635	ANISYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
636	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%.
637	ANNATTO	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.

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638	ANOGEISSUS LATIFOLIA	A, E, H	
639	ANTENNARIA DIOICA	A, E, H	
640	ANTHOCYANINS	E	
641	ANTHOXANTHUM ODORATUM	A, H	When used as an active ingredient, coumarin is a mandatory component of Anthoxanthum odoratum and the concentration of coumarin in the medicine must be no more than 0.001%.
642	ANTHRISCUS CEREFOLIUM	A, H	
643	ANTHYLLIS VULNERARIA	A, H	
644	ANTIMONY POTASSIUM TARTRATE TRIHYDRATE	H	Only for use as an active homoeopathic ingredient.
645	ANTIMONY TRISULFIDE	H	Only for use as an active homoeopathic ingredient.
646	APIUM GRAVEOLENS	A, E, H	
647	APOCYNUM CANNABINUM	A, H	The concentration of equivalent dry Apocynum cannabinum in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
648	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	H	Only for use as an active homoeopathic ingredient.
649	APPLE	E	
650	APPLE CIDER VINEGAR	E	
651	APPLE ESSENCE NATURAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
652	APPLE EXTRACT	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%.
653	APPLE FIBRE	E	
654	APRICOT	E	
655	APRICOT KERNEL OIL PEG-6 ESTERS	E	Only for use as an excipient in topical medicines for dermal application.
656	AQUILARIA MALACCENSIS	A, H	
657	AQUILARIA SINENSIS	A, H	
658	AQUILEGIA VULGARIS	A, H	
659	ARACHIDONIC ACID	E	Only for use in topical medicines for dermal application.
660	ARACHIDYL ALCOHOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
661	ARACHIDYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 0.5%.
662	ARACHIDYL PROPIONATE	E	Only for use in topical medicines for dermal application.
663	ARACHIS HYPOGAEA	A, E, H	
664	ARACHIS OIL	A, E, H	
665	ARALIA CORDATA	A, H	
666	ARALIA HISPIDA	A, H	
667	ARALIA NUDICAULIS	A, H	
668	ARALIA RACEMOSA	A, H	

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669	ARCTIUM LAPPA	A, E, H	
670	ARCTIUM MINUS	A, H	
671	ARCTOSTAPHYLOS UVA-URSI	A, E, H	<p>Beta-arbutin is a mandatory component of <i>Arctostaphylos uva-ursi</i>.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
672	ARDISIA JAPONICA	A, H	
673	ARGANIA SPINOSA KERNEL OIL	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.</p> <p>The concentration must be no more than 5% in the medicine.</p>
674	ARGININE	A, E, H	<p>Only for use in topical medicines for dermal application.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (ARGIN1) 'This medicine contains arginine and is intended to be applied to the</p>

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			skin only and not to the mucosa - vagina or rectum.'
675	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%.
676	ARISAEMA ATRORUBENS	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
677	ARISAEMA CONSANGUINEUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
678	ARISAEMA JAPONICUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
679	ARMORACIA RUSTICANA	A, E, H	Volatile oil components (of <i>Armoracia rusticana</i>) is a mandatory component of <i>Armoracia rusticana</i> . The maximum recommended daily dose must contain no more than 20 mg of volatile oil components (of <i>Armoracia rusticana</i>).
680	ARNEBIA EUCHROMA	A, H	
681	ARNICA FLOWER DRY	A, H	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than 1mg of the equivalent dry flower of <i>Arnica montana</i> .
682	ARNICA MOLLIS	A, H	When for use other than topically on unbroken skin,

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			the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
683	ARNICA MONTANA	A, H	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of arnica montana.
684	ARRHENATHERUM ELATIUS	A, H	
685	ARROWROOT	A, E, H	
686	ARSENIC TRIIODIDE	H	Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than 0.001%.
687	ARSENIC TRIOXIDE	H	Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than 0.001%.
688	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%.
689	ARTEMISIA ABSINTHIUM	A, H	Thujone is a mandatory component of Artemisia absinthium. The concentration of thujone from Artemisia absinthium in the medicine must be no more than 4%. The following warning statement is required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become

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			pregnant.’
690	ARTEMISIA ANNUA	A, H	<p>Thujone is a mandatory component of Artemisia annua.</p> <p>The concentration of thujone from Artemisia annua in the medicine must be no more than 4%.</p> <p>The following warning statement is required on the medicine label:</p> <p>- (PREGNT2) ‘Do not use if pregnant or likely to become pregnant.’</p>
691	ARTEMISIA ARBORESCENS	A, H	<p>Thujone is a mandatory component of Artemisia arborescens.</p> <p>The concentration of thujone from Artemisia arborescens in the medicine must be no more than 4%.</p>
692	ARTEMISIA ARGYI	A, H	<p>Thujone is a mandatory component of Artemisia argyi.</p> <p>The concentration of thujone from Artemisia argyi in the medicine must be no more than 4%.</p>
693	ARTEMISIA DRACUNCULUS	A, E, H	<p>Thujone is a mandatory component of Artemisia dracunculus.</p> <p>The concentration of thujone from Artemisia dracunculus in the medicine must be no more than 4%.</p>
694	ARTEMISIA FRIGIDA	A, H	<p>Thujone is a mandatory component of Artemisia frigida.</p> <p>The concentration of thujone from Artemisia frigida in the medicine must be no more than 4%.</p>

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695	ARTEMISIA HERBA-ALBA	A, H	<p>Thujone is a mandatory component of Artemisia herba-alba.</p> <p>The concentration of thujone from Artemisia herba-alba in the medicine must be no more than 4%.</p>
696	ARTEMISIA MARITIMA	A, H	<p>Thujone is a mandatory component of Artemisia maritima.</p> <p>The concentration of thujone from Artemisia maritima in the medicine must be no more than 4%.</p>
697	ARTEMISIA OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
698	ARTEMISIA PALLENS	A, E, H	<p>Thujone is a mandatory component of Artemisia pallens.</p> <p>The concentration of thujone from Artemisia pallens in the medicine must be no more than 4%.</p>
699	ARTEMISIA TRIDENTATA	A, H	<p>Thujone is a mandatory component of Artemisia tridentata.</p> <p>The concentration of thujone from Artemisia tridentata in the medicine must be no more than 4%.</p>
700	ARTEMISIA VULGARIS	A, E, H	<p>Thujone is a mandatory</p>

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			component of <i>Artemisia vulgaris</i> . The concentration of thujone from <i>Artemisia vulgaris</i> in the medicine must be no more than 4%.
701	ARTERY	H	Only for use as an active homoeopathic ingredient.
702	ARTHROSPIRA MAXIMA	A, E, H	
703	ARTHROSPIRA PLATENSIS	A, E, H	
704	ARUM MACULATUM	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
705	ASAFOETIDA GUM	A, H	
706	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%.
707	ASARUM EUROPAEUM	A, H	
708	ASARUM HETEROTROPOIDES	A, H	
709	ASARUM OIL	E	
710	ASARUM SIEBOLDII	A, E, H	
711	ASCLEPIAS TUBEROSA	A, H	
712	ASCOPHYLLUM NODOSUM	A, E, H	Iodine is a mandatory component of <i>Ascophyllum nodosum</i> . 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.

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713	ASCORBIC ACID	A, E	
714	ASCORBYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
715	ASCORBYL METHYLSILANOL PECTINATE	E	Only for use in topical medicines for dermal application.
716	ASCORBYL PALMITATE	A, E	When for oral use, the maximum recommended daily dose must contain no more than 100mg of ascorbyl palmitate.
717	ASCORBYL TOCOPHERYL MALEATE	E	Only for use as an ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0575%.
718	ASPALATHUS LINEARIS	A, E, H	
719	ASPARAGINE	A, E	
720	ASPARAGOPSIS SULFATED GALACTANS	E	Only for use as an ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0025%.
721	ASPARAGUS	E, H	Only for use as an active homoeopathic or excipient ingredient.
722	ASPARAGUS COCHINCHINENSIS	A, H	
723	ASPARAGUS OFFICINALIS	A, E, H	

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724	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.
725	ASPARTAME	E	
726	ASPARTIC ACID	A, E	
727	ASPERGILLUS ORYZAE	A, E, H	
728	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).
729	ASTER TATARICUS	A, H	
730	ASTRAGALUS ADSURGENS	A, H	
731	ASTRAGALUS COMPLANATUS	A, H	
732	ASTRAGALUS EXCARPUS	A, H	
733	ASTRAGALUS GUMMIFER	A, E, H	
734	ASTRAGALUS LENTIGINOSUS	A, H	
735	ASTRAGALUS MEMBRANACEUS	A, E, H	
736	ASTRAGALUS PENDULIFLORUS	A, H	
737	ASTROCARYUM MURUMURU SEED TRIGLYCERIDES	E	Only for use as an ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.21%.
738	ATRACTYLODES JAPONICA	A, H	
739	ATRACTYLODES LANCEA	A, H	
740	ATRACTYLODES MACROCEPHALA	A, H	
741	ATROPA BELLADONNA	A, H	Alkaloids calculated as

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			<p>hyoscyamine and atropine are mandatory components of <i>Atropa belladonna</i>.</p> <p>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%.</p> <p>The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.</p>
742	ATROPINE SULFATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
743	ATTALEA SPECIOSA	E	Only for use in topical medicines for dermal application.
744	AURA B-AURANTIOL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
745	AUREOBASIDIUM PULLULANS	A, H	
746	AVENA FATUA	A, H	Gluten is a mandatory component of <i>Avena fatua</i> when the plant part is seed and the route of administration is other than topical and mucosal.
747	AVENA SATIVA	A, E, H	Gluten is a mandatory component of <i>Avena sativa</i> when the plant part is seed and the route of administration is other than topical and mucosal.
748	AVOCADO	E	

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749	AVOCADO OIL	E	
750	AVOCADO OIL UNSAAPONIFIABLES	E	Only for use in topical medicines for dermal application.
751	AZADIRACHTA INDICA	A, H	<p>The ingredient can only be derived from the plant part seed and must be cold pressed or debitterised oil.</p> <p>“Debitterised neem seed oil” means highly purified oil from the neem seed containing only fatty acids and glycerides of fatty acids.</p> <p>Cold pressed Azadirachta indica seed oil must be for topical use for dermal application only.</p> <p>When the concentration of cold pressed Azadirachta indica seed oil is more than 1%, a child resistant closure must be fitted to the container.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect).' - (NTAKEN) 'Not to be taken (or words to that effect).' - (CHILD) 'Keep out of reach of children (or words to that effect).'
752	AZOVAN BLUE	E	Permitted for use only as a colour for topical use.
753	AZULENE	E	Only for use in topical medicines for dermal application.