

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020

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

Dated 7 December 2020

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

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1 Name

This instrument is the *Therapeutic Goods (Permissible Ingredients)* Determination (No. 4) 2020.

2 Commencement

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

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Note:	This table relates only to the provisions of this instrumen	at as originally made.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

This table relates only to the provisions of this instrument as originally made.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

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

Act means the Therapeutic Goods Act 1989.

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

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

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

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

homoeopathic preparation has the same meaning as in the Regulations.

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

Regulations means the Therapeutic Goods Regulations 1990.

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

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

- (2) To avoid doubt, the terms set out in closed brackets in column 4 of the table in Schedule 1 to this instrument, which are associated with warning statements in relation to particular ingredients, are:
 - (a) terms from the code tables under the 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 to this instrument are specified for the purposes of paragraph 26BB(1)(a) of the Act.

6 Requirements in relation to permissible ingredients being contained in medicine

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

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

transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.

7 Repeals

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

Volume 1

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

Note: See sections 5 and 6.

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

Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
5	(5Z)-3-METHYL-5- CYCLOTETRADECEN-1-ONE	Ε	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more
			than 1%.
6	(E)-2-(3,5-DIMETHYLHEX-3-EN-2- YLOXY)-2-METHYLPROPYL CYCLOPROPANECARBOXYLATE	Ε	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
7	(E)-3-METHYLCYCLOPENTADEC- 5-EN-1-ONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
8	(E, E)-2,6-NONADIENAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in 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%.
9	(R)-ALPHA-TERPINYL ACETATE	Е	(R)-alpha-terpinyl acetate must only be included in medicines when in

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	ngredients and requirements		
<u>Column 1</u>	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements combination with other permitted ingredients as a fragrance proprietary excipient formulation.
			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	А	(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

	ngredients and requirements	C -12	Colores 4
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
13	(S)-S-ADENOSYLMETHIONINE DISULFATE TRITOSYLATE DIHYDRATE	Α	 (S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tritosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
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	А	(S)-S-Adenosylmethionine is a mandatory component of

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	8		(S)-S-Adenosylmethionine hexatosylate dihydrate and must be declared in the application.
			(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
16	(S)-S-ADENOSYLMETHIONINE PENTASULFATE DIHYDRATE	А	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine pentasulfate dihydrate.
			(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			-(SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
17	(S)-S-ADENOSYLMETHIONINE PENTATOSYLATE DIHYDRATE	А	(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

Volume 1

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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	А	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine tetrasulfate dihydrate.
			(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
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

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	8		practitioner (or words to that effect)'
20	(S)-S-ADENOSYLMETHIONINE TRISULFATE DITOSYLATE DIHYDRATE	А	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine trisulfate ditosylate dihydrate.
			(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
21	(Z)-HEX-3-ENYL 2- ETHYLBUTYRATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
22	(Z, Z)-3,6-NONADIEN-1-OL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Volume 1

Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
23	1,1,1-TRICHLOROETHANE	Е	The concentration in the medicine must be no more than 25%.
24	1,2,3,4,4A,5,8,8A-OCTAHYDRO- 2,2,6,8-TETRAMETHYL-1- NAPHTHALENOL	Е	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%.
25	1,2-HEXANEDIOL	Е	Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye.
			The concentration in the medicine must be no more than 1%.
26	1,3,4,6,7,8A-HEXAHYDRO-1,1,5,5- TETRAMETHYL-2H-2,4A- METHANONAPHTHALEN-8(5H)- ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
27	1,3,5-UNDECATRIENE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
28	1,3-BUTYLENE GLYCOL	Е	
29	1,3-NONANEDIOL ACETATE, MIXED ESTERS	Ε	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total
			flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
30	1,3-NONANEDIOL, DIACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
31	1,4-CINEOLE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%
32	1,4-DIOXACYCLOHEXADECANE- 5,16-DIONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Item	ingreatent name	i ui pose	speeme requirements
33	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%.
34	1,7,7- TRIMETHYLBICYCLO[4.4.0]DECA N-3-YL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
35	1-(2,2,6- TRIMETHYLCYCLOHEXYL)-3- HEXANOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
36	1-(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%.
37	1-(3,3- DIMETHYLCYCLOHEXYL)ETHYL FORMATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more

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Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements than 1%.
38	1-(4- ISOPROPYLCYCLOHEXYL)ETHAN OL	Ε	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
39	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%.
40	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
41	1-HEPTANOL	E	 than 5%. Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.

Volume 1

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
42	1-HEXEN-3-OL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
43	1-METHOXY-4- PROPENYLBENZENE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
44	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%.
45	1-METHYL-3-(2- METHYLPROPYL)- CYCLOHEXANOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
46	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%.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
47	1-OCTEN-3-ONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
48	1-P-MENTHENE-8-THIOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
49	1-PENTEN-3-OL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
50	10-UNDECEN-1-OL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
51	10-UNDECENAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more

Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
52	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%.
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 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	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
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 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	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more

Volume 1

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%.
61	2,3,5,6-TETRAMETHYLPYRAZINE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
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	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
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	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	ingreutent nume	T ut pose	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	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
69	2,3-PENTANEDIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the tota fragrance concentration in a medicine must be no more 1%.

Volume 1

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
70	2,4,5-TRIMETHYLTHIAZOLE	Ε	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
71	2,4,6-TRIMETHYL-4-PHENYL-1,3- DIOXANE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
72	2,4-DECADIENAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.
			The maximum daily dose must provide no more than 3 mg of 2,4-Decadienal.
73	2,4-DIMETHYL BUTADIENEACROLEIN	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Volume 1

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
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	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
76	2,4-DIMETHYL-4,4A,5,9B- TETRAHYDROINDENO[1,2-D]-1,3- DIOXIN	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
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	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.
			The maximum daily dose must provide no more than 3 mg of 2,4-Heptadienal.
79	2,4-HEXADIENOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the tota fragrance concentration in the medicine must be no more than 1%.
			The maximum daily dose must provide no more than 13.5 mg of 2,4-Hexadienol.
80	2,5- DIETHYLTETRAHYDROFURAN	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
31	2,5-DIMETHYL-2-OCTEN-6-ONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%.
32	2,5-DIMETHYL-4-ETHOXY-3(2H)- FURANONE	Е	Only for use in medicines in combination with other

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	<u> </u>		permitted ingredients as a flavour proprietary excipient formulation.
			The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
33	2,5-DIMETHYL-4-HYDROXY- 3(2H)-FURANONE	Е	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%.
35	2,5-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance, or a printing ink.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
			If used in a printing ink the

Volume 1

Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			total printing ink concentration in a medicine must be no more than 0.1%
86	2,6,6,TRIMETHYL-2- CYCLOHEXENE-1,4-DIONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
87	2,6,9,10-TETRAMETHYL-1- OXASPIRO(4.5)DECA-3,6-DIENE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
88	2,6-DIMETHOXYPHENOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
89	2,6-DIMETHYL HEPTAN-2-OL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1.0.11	ingreatent nume	Turpose	Specific requirements
90	2,6-DIMETHYL-2-HEPTENAL-(7)	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a
			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
91	2,6-DIMETHYL-3,5-OCTADIEN-2- OL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
92	2,6-DIMETHYL-4-HEPTYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
93	2,6-DIMETHYLPYRAZINE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
94	2,6-NONADIEN-1-OL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
95	2,6-OCTADIENOIC ACID, 3,7- DIMETHYL-, METHYL ESTER, (2E)-	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
96	2-(1,1-DIMETHYLETHYL)-1,4- DIMETHOXY-BENZENE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
97	2-(2-(4-METHYL-3-CYCLOHEXEN- 1-YL)PROPYL CYCLOPENTANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
98	2-(2-METHYLPHENYL)ETHANOL	Е	Permitted for use only in combination with other permitted ingredients as part

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Vol	lume	1

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		1 41 9050	of a fragrance proprietary excipient formulation.
			The ingredient is not to be included in medicines intended for use in the eye.
			The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
99	2-(6-METHYL-8-ISOPROPYL BICYCLO(2.2.2)OCT-5-ENE-2-YL- 1,3-DIOXOLANE	E	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.
			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.
100	2-[(3,7-DIMETHYL-6-OCTEN-1- YLIDENE)AMINO]BENZOIC ACID, METHYL ESTER	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
101	2-[1-(3,3- DIMETHYLCYCLOHEXYL)ETHOX Y]-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%.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
102	2-[1-(3,3- DIMETHYLCYCLOHEXYL)ETHOX Y]-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%.
103	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%.
104	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%.
105	2-ACETYLPYRIDINE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
106	2-AMINO-2-METHYL-1- PROPANOL	Е	Only for use in topical medicines for dermal application.

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Vol	lume	1

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
107	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%.
108	2-BUTEN-1-OL	Ε	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
109	2-BUTYL-4,4,6-TRIMETHYL-1,3- DIOXANE	Ε	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
110	2-CYCLOHEXYLIDENE-2-O- TOLYL-ACETONITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
111	2-DECENAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%.
112	2-DODECANOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
113	2-DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
114	2-ETHOXY-4- (METHOXYMETHYL)-PHENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
115	2-ETHOXY-9-METHYLENE-2,6,6- TRIMETHYLBICYCLO[3.3.1]NONA NE	E	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.

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	ngredients and requirements Column 2	Column 3	Column 4
<u>Column 1</u> Item	Ingredient name	Purpose	Specific requirements
	Ingreulent name	1 ur pose	The total concentration of the fragrance proprietary excipient formulation containing 2-ethoxy-9- methylene-2,6,6- trimethylbicyclo[3.3.1]nonane must not be more than 1% of the total medicine.
116	2-ETHOXYETHANOL	Ε	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%.
117	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%.
118	2-ETHYL-3,5- DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
119	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

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
120	2-ETHYL-3-METHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
121	2-ETHYL-4-(2,2,3-TRIMETHYL-3- CYCLOPENTEN-1-YL)-2-BUTEN-1- OL	Ε	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
122	2-ETHYL-4-HYDROXY-5-METHYL- 3(2H)-FURANONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
123	2-ETHYL-4-METHYLTHIAZOLE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
124	2-ETHYL-ALPHA,ALPHA- DIMETHYL-BENZENEPROPANAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
125	2-ETHYL-N-METHYL-N-(3- METHYLPHENYL) BUTANAMIDE	Е	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%.
126	2-ETHYLBUTYRIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
127	2-HEPTANOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
128	2-HEPTANONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
129	2-HEPTYL CYCLOPENTANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
130	2-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
131	2-HYDROXYACETOPHENONE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.
			The concentration in the medicine must be no more

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item			
nem	Ingredient name	Purpose	Specific requirements than 1%.
132	2-ISOBUTYL-3- METHOXYPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total
			fragrance concentration in a medicine must be no more than 1%.
133	2-ISOBUTYL-4- METHYLTETRAHYDRO-2H- PYRAN-4-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
134	2-ISOPROPOXYETHYL SALICYLATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
135	2-ISOPROPYL-4- METHYLTHIAZOLE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
136	2-MERCAPTOPROPIONIC ACID	Е	Permitted for use only in combination with other

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Permissible ingredients and requirements Column 1 Column 2 Column 3 Column 4				
Item				
Item	Ingredient name	Purpose	Specific requirements permitted ingredients as a flavour.	
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
137	2-METHOXY-3-(1- METHYLPROPYL)PYRAZINE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.	
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.	
138	2-METHOXY-4-VINYLPHENOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.	
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
139	2-METHYL BUTYRIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.	
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.	
140	2-METHYL HEPTANOIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour.	
			If used in a flavour the total flavour concentration in a	

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements medicine must be no more than 5%.
141	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%.
142	2-METHYL-2-VINYL-5- ISOPROPENYLTETRAHYDROFUR AN	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
143	2-METHYL-3-(3,4- METHYLENEDIOXYPHENYL)PRO PANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in 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%.
144	2-METHYL-3-(4- METHOXYPHENYL)PROPANAL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
145	2-METHYL-3-[4-(2-	Е	Permitted for use only in

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	METHYLPROPYL)PHENYL]PROPA NAL		combination with 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-BUTEN-2-OL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
147	2-METHYL-3-FURANTHIOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
148	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%.
149	2-METHYL-4-(2,2,3-TRIMETHYL-3- CYCLOPENTENYL)-2-BUTEN-1-OL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
			Only for use in topical

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Item		rurpose	medicines for dermal application.
150	2-METHYL-4-(2,2,3- TRIMETHYLCYCLOPENT-3-EN-1- YL)PENT-4-EN-1-OL	E	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.
			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.
151	2-METHYL-4-(2,6,6-TRIMETHYL-1- CYCLOHEXEN-1-YL)-2-BUTENAL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
152	2-METHYL-4-(CAMPHENYL-8)- CYCLOHEXANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
153	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

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Permissible ingredients and requirements				
Column 1	Column 2	Column 3	Column 4	
Item	Ingredient name	Purpose	Specific requirements	
			flavour concentration in a medicine must be no more than 5%.	
154	2-METHYL-5- (METHYLTHIO)FURAN	Е	Permitted for use only in combination with other permitted ingredients as a flavour.	
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
155	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%.	
156	2-METHYLBUTYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.	
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
157	2-METHYLBUTYL ISOVALERATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.	
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
158	2-METHYLBUTYL PHENYLETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance.	

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Permissible i Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		- a. pose	If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
159	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%.
160	2-METHYLDECANAL	Ε	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%.
161	2-METHYLHEXANOIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
162	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

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Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			1%.
163	2-METHYLTETRAHYDROFURAN- 3-ONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
164	2-METHYLUNDECANAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
165	2-METHYLVALERIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
166	2-NONENAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more

Column 1	ngredients and requirements Column 2	Calumn 2	Column 4
Column 1		Column 3	
Item	Ingredient name	Purpose	Specific requirements 1%.
167	2-NONENENITRILE	Ε	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
168	2-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%.
169	2-PENTADECANONE	Ε	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%.
170	2-PENTANOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
171	2-PENTANONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		r ar pose	flavour concentration in a medicine must be no more than 5%.
172	2-PENTENAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
173	2-PENTYL FURAN	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
174	2-PHENYLPROPIONALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
175	2-PHENYLPROPIONALDEHYDE DIMETHYL ACETAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
176	2-PROPENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
177	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%.
178	2-TERT-BUTYLCYCLOHEXANOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
179	2-TERT- BUTYLCYCLOHEXYLOXY-2- BUTANOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Column 2 Ingredient name	Column 3	
Ingreuient name	Purpose	Column 4 Specific requirements
2-TRANS-6-CIS-NONADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
		If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
		If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2-TRIDECANONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
		If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
		If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2-TRIDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
		If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
		If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2-TRIDECENENITRILE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
	2-TRIDECENAL	2-TRIDECENAL E

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	8		fragrance concentration in a medicine must be no more than 1%.
184	2-UNDECENAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
185	3,3-DIMETHYL-5-(2,2,3- TRIMETHYL-3-CYCLOPENTEN-1- YL)-4-PENTEN-2-OL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
186	3,3-DIMETHYLACRYLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
187	3,4,4A,5,8,8A-HEXAHYDRO-3',7- DIMETHYLSPIRO-1,4- METHANONAPHALENE-2(1H),2'- OXIRANE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
188	3,4-DIMETHYL PHENYLACETALDEHYDE	E	3,4-Dimethyl phenylacetaldehyde must only be included in medicines when in combination with

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Column 1 Column 2 Column 3 Column 4			
Item	Ingredient name	Purpose	Specific requirements
		<u> </u>	other permitted ingredients as a fragrance proprietary excipient formulation.
			The total concentration of the fragrance proprietary excipient formulation containing 3,4-dimethyl phenylacetaldehyde must not be more than 1% of the total medicine.
189	3,4-DIMETHYL-1,2- CYCLOPENTADIONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
190	3,5,5-TRIMETHYL HEXANAL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%.
191	3,5,5-TRIMETHYLHEXYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%.
192	3,5,6,6-TETRAMETHYL-4- METHYLENEHEPTAN-2-ONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the tota fragrance concentration in a medicine must be no more

	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements than 1%.
193	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%.
194	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%.
195	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%.
196	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%.
197	3,7-DIMETHYL-1-OCTANOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
198	3,7-DIMETHYL-1-OCTEN-3-OL	Е	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%.
199	3,7-DIMETHYL-2,6- NONADIENENITRILE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
200	3,7-DIMETHYL-2,6-OCTADIENAL REACTION PRODUCTS WITH ETHANOL	Е	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-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%.

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		•	• •
202	3-(1-BUTENYL)-PYRIDINE	Ε	3-(1-Butenyl)-pyridine 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 3-(1-butenyl)- pyridine must not be more than 1% of the total medicine
203	3-(3- ISOPROPYLPHENYL)BUTANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
204	3-(4-ETHYLPHENYL)-2,2- DIMETHYLPROPANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
205	3-(4-HYDROXYPHENYL)-1-(2,4,6- TRIHYDROXYPHENYL)-1- PROPANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
206	3-(4-TERT-BUTYLPHENYL)- PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a

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	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
207	3-(ISO-CAMPHYL-5)- CYCLOHEXANOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
208	3-(METHYLTHIO)-1-HEXYL ACETATE	Ε	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
209	3-CARENE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total
210	3-DODECENAL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		1 ur pose	than 1%.
211	3-ETHYLPYRIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
212	3-HEPTYLDIHYDRO-5-METHYL- 2(3H)-FURANONE	THYL- E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
213	3-HEXANONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
214	3-HEXEN-1-OL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the tota fragrance concentration in a medicine must be no more 1%.
215	3-ISO-CAMPHYL-5- CYCLOHEXAN-1-OL	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
216	3-METHYL THIOPROPIONALDEHYDE ETHANOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
217	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%.
218	3-METHYL-5-(2,2,3-TRIMETHYL-3- CYCLOPENTEN-1-YL)-4-PENTEN- 2-OL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
219	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%.
220	3-METHYL-5-PHENYLPENTANAL	Е	Permitted for use only in

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	8	•	combination with 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- PHENYLPENTANENITRILE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
222	3-METHYL-5-PHENYLPENTANOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
223	3-METHYL-5-PROPYL-2- CYCLOHEXEN-1-ONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
224	3- METHYLCYCLOPENTADECANON E	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Volume 1

Permissible ingredients and requirements				
Column 1	Column 2	Column 3	Column 4	
Item	Ingredient name	Purpose	Specific requirements	
225	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%.	
226	3-METHYLPENTANOIC ACID	Е	3-Methylpentanoic acid must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of the flavour proprietary excipient formulation containing 3- methylpentanoic acid must not be more than 5% of the total medicine.	
227	3-METHYLTHIOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour.	
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
228	3-OCTANOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.	
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.	

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Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
229	3-OCTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
230	3-PENTYLTETRAHYDRO-2H- PYRAN-4-OL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
231	3-PHENYLPROPIONALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
232	3-PHENYLPROPYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Volume	1
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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
233	3-PHENYLPROPYL PROPIONATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
234	3-PROPYLIDENE PHTHALIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
235	3-TRANS- ISOCAMPHYLCYCLOHEXANOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
236	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%.
237	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

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Item	ingreatent name	Turpose	fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
238	4,4A,5,9B- TETRAHYDROINDENO(1,2-D)-1,3- DIOXIN	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total
			fragrance concentration in a medicine must be no more than 1%.
239	4,5-DIMETHYL-3-HYDROXY- 2(5H)FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
240	4,7-METHANO-1H- INDENEMETHANOL, OCTAHYDRO-, ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.
			The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
241	4,7-METHANO-3A,4,5,6,7,7A- HEXAHYDRO-5 (OR 6) -INDENYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
242	4,8-DIMETHYL-3,7-NONADIEN-2- OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
243	4-(1-ETHOXYVINYL)-3,3,5,5- TETRAMETHYLCYCLOHEXANON E	E	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.
			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.
244	4-(4-HYDROXY-4- METHYLPENTYL)-3- CYCLOHEXENE CARBOXALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
			A medicine that contains the ingredient must not be listed in the Register on or after 2 March 2020 or be released for supply after 2 March 2021.
245	4-(4-METHYL-3-PENTEN-1-YL)-3- CYCLOHEXENE-1- CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	ingroutent nume	Tupose	If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
246	4-(5,5,6- TRIMETHYLBICYCLO(2.2.1)HEPT- 2-YL)-CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
247	4-(METHYLTHIO)-4-METHYL-2- PENTANONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
248	4-(PARA-HYDROXYPHENYL)-2- BUTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
249	4-(PARA-METHOXYPHENYL)-2- BUTANONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
250	4-ACETYL-6-TERTIARY-BUTYL- 1,1-DIMETHYLINDAN	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
251	4-CYCLOHEXYL-2-METHYL-2- BUTANOL	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.
			The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
252	4-ETHYL GUAIACOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
253	4-HEPTANONE	E	Permitted for use only in combination with other permitted ingredients as a

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	9	•	flavour.
			If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
254	4-HYDROXYBENZALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
255	4-HYDROXYBENZYL ALCOHOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
256	4-ISOPROPYL-3-METHYLPHENOL	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 0.1%.
257	4-METHOXY-2-METHYL-2- BUTANETHIOL	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
258	4-METHYL-3-DECEN-5-OL	E	Permitted for use only in combination with other

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	ngredients and requirements Column 2	Column 3	Column 4
Column 1			
Item	Ingredient name	Purpose	Specific requirements permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
259	4-METHYL-4-MERCAPTOPENTAN- 2-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
260	4-METHYL-4-PHENYL-2-PENTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
261	4-METHYL-5-THIAZOLETHANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
262	4-METHYLBENZYLIDENE CAMPHOR	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must not be more than 4%.
			The following warning statements are required on the label:
			- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
263	4-METHYLPENTANOIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
264	4-METHYLPHENYL OCTANOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
265	4-PARA METHOXYPHENYL-3- BUTANONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
266	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%.
267	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%.
268	4-TERT-BUTYLCYCLOHEXANOL	Е	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin
			The concentration in the medicine must be no more than 0.1% .
269	4-TERT- PENTYLCYCLOHEXANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
270	5,6,7,8- TETRAHYDROQUINOXALINE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Item	ingreatent nume	i ui pose	speenie requirements
271	5,7-DIHYDRO-2-METHYLTHIENO (3,4D) PYRIMIDINE	Ε	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more
			than 5%.
272	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%.
273	5-ACETYL-1,1,2,3,3,6- HEXAMETHYL INDAN	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
274	5-CYCLOHEXADECEN-1-ONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
275	5-ETHYL-2,3- DIMETHYLPYRAZINE	E	5-Ethyl-2,3,dimethylpyrazine must not be included in medicines for oral

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Item	Ingredient name	Purpose	Specific requirementsadministration.5-Ethyl-2,3,dimethylpyrazinemust only be included intopical medicines when incombination with otherpermitted ingredients as afragrance proprietaryexcipient formulation.The total concentration of thefragrance proprietaryexcipient formulationcontaining 5-ethyl-2,3,dimethylpyrazine must nobe more than 1% of the totalmedicine.
276	5-ETHYL-3-HYDOXY-4-METHYL- 2(5H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
277	5-ETHYL-4-HYDROXY-2-METHYL- 3(2H)-FURANONE	Ε	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
278	5-HYDROXY-4- METHYLHEXANOIC ACID DELTA- LACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
279	5-METHOXYPSORALEN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
280	5-METHYL 2-PHENYL HEXEN-2- AL	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
281	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%.
282	5-METHYL-3- BUTYLTETRAHYDROPYRAN-4- YL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
283	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%.

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Permissible in	Column 1 Column 2 Column 3 Column 4		
Item			
Item	Ingredient name	Purpose	Specific requirements
284	5-PENTYL-2(5H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
285	6,6-DIMETHOXY-2,5,5- TRIMETHYL-2-HEXENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
286	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%.
287	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%.
288	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

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements than 5%.
289	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.
290	6-METHOXY-2,6- DIMETHYLHEPTAN-1-AL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%.
291	6- METHOXYDICYCLOPENTADIENE CARBOXALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.
			When included in a medicine for use on the lips the concentration of 6- methoxydicyclopentadiene carboxaldehyde must be no more than 0.1%.
			When included in dermal creams for infant use the concentration of 6- methoxydicyclopentadieneca boxaldehyde must be no mor

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 0.5%.
			When for dermal use or use or the hair the concentration of 6- methoxydicyclopentadienecar boxaldehyde must be no more than 0.5%.
			The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
292	6-METHYL COUMARIN	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
293	6-METHYL-2-BUTEN-3-OL-2	Е	
	6-METHYLQUINOLINE	E	6-Methylquinoline must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.
			The total concentration of the flavour proprietary excipient formulation containing 6-methylquinoline must not be more than 5% of the total medicine.
295	7-ACETYL-1,1,3,4,4,6- HEXAMETHYL TETRAHYDRONAPHTHALENE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
296	7-METHYL-2H-1,5- BENZODIOXEPIN-3(4H)-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total
			flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
297	7-OCTENE-1,6-DIOL, 3,7- DIMETHYL-	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
298	7-PROPYL-2H-1,5- BENZODIOXEPIN-3(4H)-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
299	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%.
300	8-METHYL-1- OXASPIRO(4,5)DECAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
301	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%.
302	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%.
303	ABELMOSCHUS MOSCHATUS	A, H	
304	ABELMOSCHUS MOSCHATUS SUBSP. MOSCHATUS	A, H	
305	ABIES BALSAMEA	A, H	
306	ABIES NIGRA	A, H	
307	ABIES PECTINATA	A, H	
308	ABIES SIBIRICA	A, H	
309	ABRUS CANTONIENSIS	А, Н	If the herbal substance is derived from the seed, the maximum recommended daily dose of Abrus cantoniensis must be no more than 1mg of the dry seed.
310	ABUTILON THEOPHRASTI	A, H	
311	ACACIA	A, E, H	
312	ACACIA BAILEYANA	А, Н	
		,	

	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
314	ACACIA DEALBATA	A, H	
315	ACACIA DECURRENS	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total
			flavour concentration in a medicine must be no more than 5%.
316	ACACIA FARNESIANA	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
317	ACACIA LONGIFOLIA	A, E, H	
318	ACACIA NILOTICA	А, Е, Н	
319	ACACIA SENEGAL	А, Е, Н	
320	ACALYPHA INDICA	A, H	
321	ACANTHUS MOLLIS	A, H	
322	ACER CAMPESTRE	A, H	
323	ACER NEGUNDO	A, H	
324	ACER SACCHARINUM	A, H	
325	ACER SACCHARUM	А, Е, Н	
326	ACEROLA	Е	
327	ACESULFAME POTASSIUM	Е	
328	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%.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
329	ACETALDEHYDE	Ε	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
330	ACETALDEHYDE ETHYL LINALYL ACETAL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
331	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%.
332	ACETALDEHYDE PHENYLETHYL PROPYL ACETAL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
333	ACETANISOLE	Е	Permitted for use only: (a) in topical medicines for dermal application; and

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		(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%.
334	ACETIC ACID	E, H	The concentration in the medicine must be no more than 80%.
335	ACETOIN	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
336	ACETOMENAPHTHONE	A, E	
337	ACETONE	Е	The residual solvent limit for Acetone is 50 mg per maximum recommended daily dose.
			The concentration in the medicine must be no more than 0.5%.
338	ACETOPHENONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
339	ACETOVANILLONE	E	Only for use in topical medicines for dermal application. Permitted for use only in combination with other permitted ingredients as a fragrance. If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.
340	ACETOXYDIHYDRODICYCLOPEN TADIENE	Ε	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%.
341	ACETYL	Ε	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
342	ACETYL DIPEPTIDE-1 CETYL ESTER	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		1 ui pose	than 0.01%.
343	ACETYL GLUCOSAMINE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 0.5%.
			If the ingredient is sourced from seafood, then the medicine requires the following warning statement on the medicine label:
			- (SFOOD) 'Derived from seafood'
344	ACETYL HEXAMETHYL TETRALIN	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%.
345	ACETYL LEVOCARNITINE HYDROCHLORIDE	Α, Ε	
346	ACETYL TRIFLUOROMETHYLPHENYL VALYLGLYCINE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 0.5%.
347	ACETYLATED LANOLIN	E	Only for use in topical medicines for dermal application.
348	ACETYLATED LANOLIN	Е	Only for use in topical

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Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	ALCOHOL		medicines for dermal application.
349	ACETYLATED MONOGLYCERIDES	E	
350	ACETYLATED VETIVER OIL	Ε	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
351	ACETYLCYSTEINE	E	Only for use in topical medicines for dermal application.
			The concentration in the medicine must be no more than 0.001%.
352	ACHILLEA ERBA-ROTTA SUBSP. MOSCHATA	A, H	
353	ACHILLEA MILLEFOLIUM	А, Е, Н	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

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
354	ACHILLEA PTARMICA	A, H	
355	ACHYRANTHES ASPERA	A, H	
356	ACHYRANTHES BIDENTATA	A, H	
357	ACHYRANTHES FAURIEI	A, H	
358	ACID GREEN 25	Е	Permitted for use only as a colour for topical use.
359	ACID RED 33	Е	Permitted for use only as a colour for topical use.
360	ACID RED 87	Е, Н	Only for use as an active homoeopathic ingredient or for excipient use as a colour in topical medicines.
361	ACID TREATED WAXY MAIZE STARCH	E	
362	ACID-ISOMERISED LINALOOL	Ε	Permitted for use only when combined with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
363	ACONITUM CARMICHAELII	А, Н	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum carmichaelii. The maximum amount of tota alkaloids (of Aconitum spp.)
364	ACONITUM FEROX	А, Н	The maximum amoun

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Permissible ingredients and requirements Column 1 Column 2 Column 3 Column 4			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirementsspp.) is a mandatorycomponent of Aconitumferox.The maximum amount of totalalkaloids (of Aconitum spp.)must be no more than 0.02milligrams per pack.
365	ACONITUM KUSNEZOFFI	А, Н	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum kusnezoffii.
			The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
366	ACONITUM NAPELLUS	А, Н	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum napellus.
			The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
367	ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 1.7%.
368	ACRYLAMIDES COPOLYMER	Е	Only for use in topical medicines for dermal application.
369	ACRYLATES COPOLYMER	Е	Only for use in topical medicines for dermal application.
370	ACRYLATES/ACRYLAMIDE	Е	Only for use in topical

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name COPOLYMER	Purpose	Specific requirements medicines for dermal application.
371	ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
372	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%.
373	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%.
374	ACRYLATES/OCTYLACRYLAMID E COPOLYMER	Е	Only for use in topical medicines for dermal application.
375	ACRYLATES/STEARETH-20 METHACRYLATE COPOLYMER	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 1%.
376	ACRYLATES/VA COPOLYMER	E	Only for use in topical medicines for dermal application.
377	ACRYLIC ACID/VP	Е	Only for use in topical

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	CROSSPOLYMER	1 ui pose	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%.
378	ACTAEA CIMICIFUGA	A, H	
379	ACTAEA HERACLEIFOLIA	A, H	
380	ACTAEA PACHYPODA	A, H	
381	ACTAEA RACEMOSA	А, Н	When used in oral medicines, the medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
382	ACTAEA SIMPLEX	A, H	
383	ACTAEA SPICATA	A, H	
384	ACTINIDIA CHINENSIS	A, H	
385	ACTINIDIA DELICIOSA	A, H	
386	ACTIVATED ATTAPULGITE	Α	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
387	ACTIVATED CHARCOAL	A, E, H	When for internal use, the

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Column 1	ngredients and requirements Column 2	Column 2	Column 4
		Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements 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).
388	ADEMETIONINE DISULFATE DITOSYLATE DIHYDRATE	А, Н	(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)'
389	ADEMETIONINE DISULFATE TOSYLATE	А, Н	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate tosylate.
			Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from

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Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
390	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)'	
391	ADEMETIONINE HEXASULFATE DIHYDRATE	A, H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine hexasulfate dihydrate.
			Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
392	ADEMETIONINE HEXATOSYLATE	A, H	(S)-S-Adenosylmethionine is

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	DIHYDRATE		a mandatory component of Ademetionine hexatosylate dihydrate.
			Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
393	ADEMETIONINE PENTASULFATE DIHYDRATE	А, Н	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine pentasulfate dihydrate.
			Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription 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 PENTATOSYLATE DIHYDRATE	А, Н	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine pentatosylate dihydrate.
			Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
395	ADEMETIONINE TETRASULFATE DIHYDRATE	А, Н	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine tetrasulfate dihydrate.
			Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
396	ADEMETIONINE TETRATOSYLATE DIHYDRATE	А, Н	(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

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			effect)'
397	ADEMETIONINE TRISULFATE DITOSYLATE DIHYDRATE	А, Н	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine trisulfate ditosylate dihydrate.
			(S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:
			- (SAME) 'Individuals who are using prescription anti- depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'

398	ADENOPHORA STRICTA	A, H	
399	ADENOPHORA TRIPHYLLA	A, H	
400	ADENOSINE	Ε	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.
			The concentration in the medicine must be no more than 0.04%.
401	ADENOSINE PHOSPHATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 0.1%.
402	ADENOSINE TRIPHOSPHATE	E	Only for use in topical medicines for dermal

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Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			application.
403	ADENOSINE TRIPHOSPHATE DISODIUM	Е	Only for use in topical medicines for dermal application.
404	ADIANTUM CAPILLUS-VENERIS	A, H	
405	ADIPIC ACID	Е	
406	ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 5%.
407	ADONIS VERNALIS	А, Н	The concentration of equivalent dry Adonis vernalis in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
408	ADRENALINE (EPINEPHRINE)	Н	Only for use as an active homoeopathic ingredient.
409	ADZUKI BEAN	Е	
410	AEGOPODIUM PODAGRARIA	A, H	
411	AESCULUS CHINENSIS	A, H	
412	AESCULUS GLABRA	A, H	
413	AESCULUS HIPPOCASTANUM	A, H	
414	AESCULUS X CARNEA	A, H	
415	AETHUSA CYNAPIUM	Н	Only for use as an active homoeopathic ingredient.
416	AGAR	A, E	
417	AGASTACHE RUGOSA	A, H	
418	AGATHOSMA BETULINA	A, E, H	Pulegone is a mandatory component of Agathosma betulina.
			The concentration of pulegone

435

436

437

Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			in the medicine must be no more than 4%.
419	AGAVE AMERICANA	A, E, H	
420	AGRIMONIA EUPATORIA	А, Е, Н	
421	AGRIMONIA REPENS	A, H	
422	AGROSTIS TENUIS	A, H	
423	AILANTHUS ALTISSIMA	A, H	
424	AJUGA CHAMAEPITYS	A, H	
425	AJUGA REPTANS	A, H	
426	ALANINE	A, E	
427	ALANYLGLUTAMINE	А	Only for use in oral medicines.
428	ALARIA ESCULENTA	А, Н	Iodine is a mandatory component of Alaria esculenta.
			Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.
			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
429	ALBIZIA JULIBRISSIN	A, H	
430	ALBIZIA LEBBECK	A, H	
431	ALCEA ROSEA	A, H	
432	ALCHEMILLA ALPINA	A, H	
433	ALCHEMILLA ARVENSIS	A, H	

A, H

A, H

<u>A, H</u>

Е

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020

ALCHEMILLA VULGARIS

ALEURITES MOLUCCANUS SEED

ALETRIS FARINOSA

ALETRIS SPICATA

OIL

Only for use in topical

medicines for dermal

application.

Volume 1

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Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
438	ALFADEX	A, E	Only for use in oral medicines.
			The maximum daily dose must provide no more than 6 g of alfadex.
439	ALGINATE-KONJAC-XANTHAN POLYSACCHARIDE COMPLEX	А	Only for use in oral medicines.
			Only for use when the dosage form is other than tablet.
			The maximum recommended daily dose must be no more than 13.5 g.
			When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:
			- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
			When a dose for children is stated, the medicine requires the following warning statement on the medicine label:
			- (PSYLL) 'On medical advice' (or words to that effect).

440	ALGINIC ACID	Е	
441	ALISMA ORIENTALE	A, H	
442	ALISMA PLANTAGO AQUATICA	A, H	
443	ALKANNA TINCTORIA	A, H	
444	ALKYL (C12-15) BENZOATE	Ε	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Volume 1
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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			The concentration in the medicine must be no more than 21%.
445	ALLANTOIN	Е	Only for use in topical medicines for dermal application.
446	ALLIARIA PETIOLATA	A, H	
447	ALLIUM CEPA	A, H	
448	ALLIUM FISTULOSUM	A, H	
449	ALLIUM HIEROCHUNTINUM	A, H	
450	ALLIUM MACROSTEMON	A, H	
451	ALLIUM ODORUM	A, H	
452	ALLIUM PORRUM	A, H	
453	ALLIUM SATIVUM	A, E, H	
454	ALLIUM SCHOENOPRASUM	A, H	
455	ALLIUM URSINUM	A, H	
456	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%.
457	ALLURA RED AC	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
458	ALLURA RED AC ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use
459	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

# Volume 1

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements medicine must be no more than 5%. If used in a fragrance the total
			fragrance concentration in a medicine must be no more 1%.
460	ALLYL AMYL GLYCOLATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
461	ALLYL CAPRYLATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
462	ALLYL CYCLOHEXANEPROPIONATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
463	ALLYL CYCLOHEXYLOXYACETATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Item		1 ui pose	medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
464	ALLYL HEPTANOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
465	ALLYL HEPTYLATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
466	ALLYL HEXANOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
467	ALLYL ISOTHIOCYANATE	Е	Permitted for use only in combination with other

# Volume 1

	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements 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%.
468	ALLYL PHENOXYACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
469	ALLYL TIGLATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
470	ALMOND	Е	
471	ALMOND OIL	А, Е, Н	Amygdalin and hydrocyanic acid are mandatory components of Almond oil. The concentration of
			Amygdalin in the medicine must be 0%.
			The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%

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	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
472	ALNUS GLUTINOSA	A, H	
473	ALNUS INCANA SUBSP. RUGOSA	A, H	
474	ALOE FEROX	А, Е, Н	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe ferox.
			When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:
			- (CHILD3) 'Use in children under 12 years is not recommended';
			- (LAX2) 'Prolonged use may cause serious bowel problems'; and
			- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].
			When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:
			- (LAX1) 'Drink plenty of water' [or words to that effect].
			When not promoted or marketed as laxative, the medicine requires the following warning statements

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Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1.0.11		1 11 1000	on the medicine label:
			<ul> <li>(LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>(LAX4) 'This product may have laxative effect'.</li> </ul>
			When used in oral medicines, if the maximum recommende daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted o 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'.
475	ALOE PERRYI	A, H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Alo perryi.
			When used in oral medicines, if the maximum recommende daily dose contains more thar 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';

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<ul> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when</li> </ul>
			abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcard 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 recommender daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted o 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

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			effect]; and
			- (LAX2) 'Prolonged use may cause serious bowel problems'.
476	ALOE VERA	A, E, H	<ul> <li>When the route of administration is oral or sublingual,</li> <li>Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloo vera.</li> <li>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: <ul> <li>(CHILD3) 'Use in children under 12 years is not recommended';</li> <li>(LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>(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].</li> </ul> </li> <li>When promoted or marketed as a laxative, the medicine label: <ul> <li>(LAX1) 'Drink plenty of water' [or words to that effect].</li> </ul> </li> </ul>

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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'.
			<ul> <li>When used in oral medicines, if the maximum recommended aily dose contains less than 10 mg of hydroxyanthracened erivatives and is promoted of marketed as laxative, the medicine requires the following warning statements on the medicine label:</li> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
477	ALOES CAPE	A, H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloes cape. When used in oral medicines, if the maximum recommende daily dose contains more than
			<ul> <li>10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</li> <li>- (CHILD3) 'Use in children</li> </ul>

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			under 12 years is not recommended';
			- (LAX2) 'Prolonged use may cause serious bowel problems'; and
			<ul> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if yo develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcar professional before taking thi product' [or words to that effect].</li> </ul>
			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 recommende daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted of 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

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		•	water' [or words to that effect]; and
			- (LAX2) 'Prolonged use may cause serious bowel problems'.
478	ALOYSIA CITRODORA	A, H	
479	ALPHA CASOZEPINE ENRICHED HYDROLYSED MILK PROTEIN	А	Only for use in oral medicines.
			The medicine requires the following warning statements on the medicine label:
			- (BABY3) 'Not suitable for use in children under the age of twelve months - except on professional advice'
			- (COWMK) 'Derived from cow's milk.'
480	ALPHA LIPOIC ACID	А	
481	ALPHA-2,2,6-TETRAMETHYL- CYCLOHEXENEBUTANAL	Е	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.
			The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
482	ALPHA-AMYL CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

# Volume 1

I el importe m	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
483	ALPHA-AMYL CINNAMYL ALCOHOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
484	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%.
485	ALPHA-DAMASCONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
486	ALPHA-FARNESENE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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	ngredients and requirements	~	~
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
487	ALPHA-FURFURYL OCTANOATE	Ε	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
488	ALPHA- HEXYLCINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
489	ALPHA-IONOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
490	ALPHA-IONONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total

# Volume 1

	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			fragrance concentration in a medicine must be no more 1%.
491	ALPHA-IRONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
492	ALPHA-ISO-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
493	ALPHA-METHYL ANISALACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
494	ALPHA-METHYL BENZYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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Permissible in Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Ittm		Turpose	If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
495	ALPHA-METHYL BUTYRALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
496	ALPHA-METHYL BUTYRIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
497	ALPHA-METHYL CINNAMALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
498	ALPHA-METHYL FURFURAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

# Volume 1

Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
499	ALPHA-METHYL NAPHTHYL KETONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
500	ALPHA-METHYLCINNAMYL ALCOHOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
501	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%.
502	ALPHA-PHELLANDRENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Volume	1
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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
503	ALPHA-PINENE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
504	ALPHA-SANTALOL	Е	alpha-Santalol 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 alpha-santalol must not be more than 1% of the total medicine.
505	ALPHA-SINENSAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
506	ALPHA-TERPINENE	Е	Permitted for use only in combination with other permitted ingredients as a

Volume 1

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
507	ALPHA-TERPINEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
508	ALPINIA GALANGA	A, H	
509	ALPINIA HAINANENSIS	A, H	
510	ALPINIA OFFICINARUM	A, H	
511	ALPINIA OXYPHYLLA	A, H	
512	ALSIDIUM HELMINTHOCHORTON	А, Н	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.
513	ALSTONIA BOONEI	A, H	
514	ALSTONIA CONSTRICTA	Н	Only for use as an active

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020

Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Item		1 ui pose	homoeopathic ingredient.
515	ALTERNANTHERA PHILOXEROIDES	A, H	
516	ALTEROMONAS FERMENT EXTRACT	Ε	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye.
			The concentration in the medicine must be no more than 0.3%.
517	ALTHAEA OFFICINALIS	A, E, H	
518	ALUM DODECAHYDRATE	А, Е, Н	
519	ALUMINIUM CHLOROHYDRATE	E	Only for use in topical medicines for dermal application.
520	ALUMINIUM CITRATE	Е	Only for use in topical medicines for dermal application.
521	ALUMINIUM DISTEARATE	Е	Only for use in topical medicines for dermal application.
522	ALUMINIUM HYDROXIDE	Е	Only for use in topical medicines for dermal application.
523	ALUMINIUM HYDROXIDE HYDRATE	Е	Only for use in topical medicines for dermal application.
524	ALUMINIUM MAGNESIUM SILICATE	Е	
525	ALUMINIUM MONOSTEARATE	E	Only for use in topical medicines for dermal application.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
526	ALUMINIUM OXIDE	Е, Н	When used as an excipient ingredient, only for use in topical medicines for dermal application.
			When used as an active ingredient, only for use in homoeopathic medicines.
527	ALUMINIUM SILICATE	E, H	Only for use as an active homoeopathic or excipient ingredient.
			When used as an excipient ingredient, the medicine is only for use in topical medicines for dermal application.
528	ALUMINIUM SODIUM SILICATE	Ε	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
529	ALUMINIUM STARCH OCTENYLSUCCINATE	Е	The concentration in the medicine must be no more than 7%.
530	ALUMINIUM STEARATE	E	Only for use in topical medicines for dermal application.
531	ALUMINIUM SULFATE HYDRATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item			
Item	Ingredient name	Purpose	Specific requirements flavour concentration in a medicine must be no more than 5%.
532	AMARANTH	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
533	AMARANTH ALUMINIUM LAKE	Е	Permitted for use only as a colour for oral and topical use
534	AMARANTHUS HYBRIDUS	A, H	
535	AMARANTHUS RETROFLEXUS	A, H	
536	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%.
537	AMBRETTE SEED OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
538	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 tota fragrance concentration in a medicine must be no more 1%.

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Permissible ingredients and requirements				
Column 1	Column 2	Column 3	Column 4	
Item	Ingredient name	Purpose	Specific requirements	
539	AMBRINOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.	
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.	
540	AMBROSIA ARTEMISIIFOLIA	A, H		
541	AMBROSIA PSILOSTACHYA	A, H		
542	AMINOBENZOIC ACID	А	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%.	
543	AMINOCAPROIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour.	
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.	
544	AMINOPROPYL ASCORBYL PHOSPHATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.	
			The concentration in the medicine must be no more than 0.1%.	
545	AMMI VISNAGA	А, Н	The concentration of equivalent dry Ammi visnaga	

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	9		in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
546	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%.
547	AMMONIO METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
548	AMMONIUM ACRYLATES COPOLYMER	Е	Only for use in topical medicines for dermal application.
549	AMMONIUM ACRYLATES/ACRYLONITROGENS COPOLYMER	Е	Only for use in topical medicines for dermal application.
550	AMMONIUM ACRYLOYLDIMETHYLTAURATE/ STEARETH-8 METHACRYLATE COPOLYMER	Е	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.
			The concentration in the medicine must be no more than 0.5%.
551	AMMONIUM ACRYLOYLDIMETHYLTAURATE/ VP COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.
			The concentration in the medicine must be no more

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%.
552	AMMONIUM BICARBONATE	А, Н	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.
553	AMMONIUM BROMIDE	Н	Only for use as an active homoeopathic ingredient.
554	AMMONIUM CARBONATE	Е, Н	Only for use as an active homoeopathic or excipient ingredient.
555	AMMONIUM CHLORIDE	А, Е, Н	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.
556	AMMONIUM GLYCYRRHIZINATE	Е	
557	AMMONIUM IODIDE	Н	Only for use an active ingredient in homoeopathic medicines.
558	AMMONIUM LACTATE	Е	Only for use in topical

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	0		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%.
559	AMMONIUM LAURETH SULFATE	Ε	Only for use in topical medicines for dermal application.
560	AMMONIUM LAURYL SULFATE	Е	Only for use in topical medicines for dermal application.
561	AMMONIUM POLYACRYLATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 0.2%.
562	AMMONIUM POLYACRYLOYLDIMETHYL TAURATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration must be no more than 3%.
563	AMMONIUM SULFIDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
564	AMOMUM AROMATICUM	A, H	

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Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
565	AMOMUM VILLOSUM	A, H	
566	AMORPHOPHALLUS KONJAC	А, Н	Only for use when the dosage form is not tablet.
567	AMPELODESMOS MAURITANICUS	А, Н	
568	AMPELOPSIS JAPONICA	A, H	
569	AMYL ACETATE	Е	Only for use in:
			<ul> <li>topical medicines for dermal application; or</li> <li>combination with other permitted ingredients as a flavour proprietary excipient formulation.</li> </ul>
			The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
570	AMYL ALCOHOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
571	AMYL BENZOATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
572	AMYL BUTYRATE	Е	Permitted for use only in

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	<u>g</u> . earen mune		combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in 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%.
573	AMYL CAPROATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
574	AMYL CINNAMATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
575	AMYL CINNAMIC ALCOHOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
576	AMYL FORMATE	E	Permitted for use only in

# Volume 1

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more
			than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
577	AMYL ISOBUTYRATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
578	AMYL ISOVALERATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
579	AMYL OCTANOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
580	AMYL PHENYLACETATE	E	Permitted for use only in

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		T ur pose	combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
581	AMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
582	AMYL SALICYLATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
583	AMYL VALERATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
584	AMYL VINYL CARBINOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total

# Volume 1

Permissible in	ngredients and requirements	Permissible ingredients and requirements				
Column 1	Column 2	Column 3	Column 4			
Item	Ingredient name	Purpose	Specific requirements			
			fragrance concentration in a medicine must be no more 1%.			
585	AMYL VINYL CARBINYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.			
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.			
			If used in a fragrance the tota fragrance concentration in a medicine must be no more 1%.			
586	AMYLASE	А	Amylase must be derived from Aspergillus oryzae, and comply with the relevant compositional guideline.			
			When used in a divided preparation, the allowed unit is Alpha-amylase dextrinising unit or Thousand alpha- amylase dextrinising unit.			
			When used as an undivided preparation, the allowed unit is Thousand alpha-amylase dextrinising unit per gram or Dextrinising unit per gram.			
587	AMYLCYCLOHEXYL ACETATE (MIXED ISOMERS)	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.			
			If used in a fragrance the tota fragrance concentration in a medicine must be no more than 1%.			
588	AMYLOPECTIN	Е	Permitted for use only in combination with other permitted ingredients as a flavour.			

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
589	AMYRIS BALSAMIFERA	A, H	
590	AMYRIS OIL WEST INDIAN	A, E, H	
591	ANACARDIUM OCCIDENTALE	A, H	
592	ANACYCLUS PYRETHRUM	А, Н	
593	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%.
594	ANAESTHETIC ETHER	Н	Only for use as an active homoeopathic ingredient.
595	ANAGALLIS ARVENSIS	A, H	
596	ANAMIRTA COCCULUS	А, Н	Picrotoxin is a mandatory component of Anamirta cocculus.
			The concentration of picrotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%
597	ANANAS COMOSUS	A, E, H	
598	ANAPHALIS SINICA	A, H	
599	ANDROGRAPHIS PANICULATA	А, Н	The following warning statement is required on the label:
			- (ANDROG) 'Andrographis may cause allergic reactions i some people. If you have a severe reaction (such as anaphylaxis) stop use and see immediate medical attention' (or words to that effect).

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Column 1	ngredients and requirements Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Ittil	Ingredient name	1 ui pose	Specific requirements
600	ANEMARRHENA ASPHODELOIDES	А, Е, Н	
601	ANEMONE ALTAICA	A, H	
602	ANEMONE CHINENSIS	A, H	
603	ANEMONE HEPATICA	A, H	
604	ANEMONE PULSATILLA	A, H	
605	ANEMONE RADDEANA	A, H	
606	ANETHOLE	Е	
607	ANETHOLEA ANISATA	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
608	ANETHUM GRAVEOLENS	А, Е, Н	
609	ANGELICA ACUTILOBA	A, H	
610	ANGELICA ANOMALA	A, H	
611	ANGELICA ARCHANGELICA	А, Е, Н	
612	ANGELICA ATROPURPUREA	A, H	
613	ANGELICA DAHURICA	А, Е, Н	
614	ANGELICA DECURSIVA	А, Н	
615	ANGELICA POLYMORPHA	А, Е, Н	
616	ANGELICA PUBESCENS	А, Е, Н	
617	ANGELICA ROOT DRY	А, Н	
618	ANGELICA ROOT OIL	А, Е, Н	
619	ANGELICA SEED OIL	A, E, H	
620	ANGELICA STEM	Е	
621	ANIBA ROSAEODORA	А, Е, Н	
622	ANISALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	<b>9</b> • * • • • •		If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
623	ANISE ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
624	ANISE OIL	А, Е, Н	When the concentration of Anise oil in the preparation is more than 50% the nominal capacity of the container must be no more than 50 mL.
			When the concentration of Anise oil in the preparation is more than 50% and the nominal capacity of the container is 50 mL or less, a restricted flow insert must be fitted on the container.
			The medicine requires the following warning statement on the medicine label:
			- (CHILD) 'Keep out of reach of children (or word to that effect)'
625	ANISEED	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more

# Volume 1

Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
626	ANISEED DRY	A, E, H	
627	ANISEED POWDER	А, Е, Н	
628	ANISIC ACID	Ε	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
629	ANISYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
630	ANISYL ACETONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the tota fragrance concentration in a medicine must be no more 1%.
631	ANISYL FORMATE	Е	Permitted for use only in

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		1	combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in 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%.
632	ANISYL PROPIONATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
633	ANNATTO	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
634	ANOGEISSUS LATIFOLIA	А, Е, Н	
635	ANTENNARIA DIOICA	A, E, H	
636	ANTHOCYANINS	E	
637	ANTHOXANTHUM ODORATUM	А, Н	When used as an active ingredient, coumarin is a mandatory component of Anthoxanthum odoratum and the concentration of coumarin in the medicine must be no more than 0.001%.
638	ANTHRISCUS CEREFOLIUM	A, H	
639	ANTHYLLIS VULNERARIA	A, H	
640	ANTIMONY POTASSIUM TARTRATE TRIHYDRATE	Н	Only for use as an active homoeopathic ingredient.
641	ANTIMONY TRISULFIDE	Н	Only for use as an active

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	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			homoeopathic ingredient.
642	APIUM GRAVEOLENS	A, E, H	
643	APOCYNUM CANNABINUM	А, Н	The concentration of equivalent dry Apocynum cannabinum in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
644	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	Н	Only for use as an active homoeopathic ingredient.
645	APPLE	Е	
646	APPLE CIDER VINEGAR	Е	
647	APPLE ESSENCE NATURAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
648	APPLE EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
649	APPLE FIBRE	Е	
650	APRICOT	Е	
651	APRICOT KERNEL OIL PEG-6 ESTERS	Е	Only for use as an excipient ir topical medicines for dermal application.
652	AQUILARIA MALACCENSIS	A, H	
653	AQUILARIA SINENSIS	A, H	
654	AQUILEGIA VULGARIS	A, H	

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
655	ARACHIDONIC ACID	E	Only for use in topical medicines for dermal application.
656	ARACHIDYL ALCOHOL	Ε	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
657	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%.
658	ARACHIDYL PROPIONATE	E	Only for use in topical medicines for dermal application.
659	ARACHIS HYPOGAEA	A, E, H	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
660	ARACHIS OIL	А, Е, Н	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
661	ARALIA CORDATA	A, H	
662	ARALIA HISPIDA	A, H	
663	ARALIA NUDICAULIS	A, H	

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Permissible in	igredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
664	ARALIA RACEMOSA	A, H	
665	ARCTIUM LAPPA	А, Е, Н	
666	ARCTIUM MINUS	A, H	
667	ARCTOSTAPHYLOS UVA-URSI	А, Е, Н	Beta-arbutin is a mandatory component of Arctostaphylos uva-ursi.
			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%.
668	ARDISIA JAPONICA	A, H	
669	ARECA CATECHU	A, H	Arecoline is a mandatory component of Areca catechu.
			The concentration of arecoline in the medicine must be no more than 10 mg/Kg or 10 mg/L or 0.001%.
670	ARGANIA SPINOSA KERNEL OIL	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
		1 419000	The concentration must be no more than 5% in the medicine
671	ARGININE	А, Е, Н	Only for use in topical medicines for dermal application.
			The medicine requires the following warning statement on the medicine label:
			- (ARGIN1) 'This medicine contains arginine and is intended to be applied to the skin only and not to the mucosa - vagina or rectum.'
672	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%.
673	ARISAEMA ATRORUBENS	А, Н	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
674	ARISAEMA CONSANGUINEUM	А, Н	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
675	ARISAEMA JAPONICUM	А, Н	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
676	ARMORACIA RUSTICANA	А, Е, Н	Volatile oil components (of Armoracia rusticana) is a mandatory component of Armoracia rusticana.

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Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			The maximum recommended daily dose must contain no more than 20 mg of volatile oil components (of Armoracia rusticana).
677	ARNEBIA EUCHROMA	A, H	
678	ARNICA FLOWER DRY	А, Н	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than 1mg of the equivalent dry flower of Arnica montana.
679	ARNICA MOLLIS	А, Н	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
680	ARNICA MONTANA	А, Н	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of arnica montana.
681	ARRHENATHERUM ELATIUS	A, H	
682	ARROWROOT	А, Е, Н	
683	ARSENIC TRIIODIDE	Н	Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than 0.001%.
684	ARSENIC TRIOXIDE	Н	Only for use as an active homoeopathic ingredient.
			The concentration of arsenic in the medicine must be no more than 0.001%.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
Item		T ut pose	specific requirements
685	ARTEMISIA ABROTANUM	А, Н	Thujone is a mandatory component of Artemisia abrotanum. The concentration of thujone from Artemisia abrotanum in the medicine must be no more than 4%.
686	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%.
687	ARTEMISIA ANNUA	А, Н	Thujone is a mandatory component of Artemisia annua.
			The concentration of thujone from Artemisia annua in the medicine must be no more than 4%.
688	ARTEMISIA ARBORESCENS	А, Н	Thujone is a mandatory component of Artemisia arborescens.
			The concentration of thujone from Artemisia arborescens in the medicine must be no more than 4%.
689	ARTEMISIA ARGYI	А, Н	Thujone is a mandatory component of Artemisia argyi.
			The concentration of thujone from Artemisia argyi in the medicine must be no more than 4%.
690	ARTEMISIA DRACUNCULUS	А, Е, Н	Thujone is a mandatory component of Artemisia dracunculus.
			The concentration of thujone

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	ngredients and requirements	C. 1	Calana A
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements from Artemisia dracunculus in the medicine must be no more than 4%.
691	ARTEMISIA FRIGIDA	А, Н	Thujone is a mandatory component of Artemisia frigida. The concentration of thujone
			from Artemisia frigida in the medicine must be no more than 4%.
692	ARTEMISIA HERBA-ALBA	А, Н	Thujone is a mandatory component of Artemisia herba-alba.
			The concentration of thujone from Artemisia herba-alba in the medicine must be no more than 4%.
693	ARTEMISIA MARITIMA	А, Н	Thujone is a mandatory component of Artemisia maritima.
			The concentration of thujone from Artemisia maritima in the medicine must be no more than 4%.
694	ARTEMISIA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
695	ARTEMISIA PALLENS	А, Е, Н	Thujone is a mandatory component of Artemisia

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			pallens.
			The concentration of thujone from Artemisia pallens in the medicine must be no more than 4%.
696	ARTEMISIA TRIDENTATA	А, Н	Thujone is a mandatory component of Artemisia tridentata.
			The concentration of thujone from Artemisia tridentata in the medicine must be no more than 4%.
697	ARTEMISIA VULGARIS	A, E, H	Thujone is a mandatory component of Artemisia vulgaris.
			The concentration of thujone from Artemisia vulgaris in the medicine must be no more than 4%.
698	ARTERY	Н	Only for use as an active homoeopathic ingredient.
699	ARTHROSPIRA MAXIMA	A, E, H	
700	ARTHROSPIRA PLATENSIS	A, E, H	
701	ARUM MACULATUM	А, Н	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
702	ASAFOETIDA GUM	A, H	
703	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%.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
704	ASARUM EUROPAEUM	A, H	
705	ASARUM HETEROTROPOIDES	A, H	
706	ASARUM OIL	Е	
707	ASARUM SIEBOLDII	А, Е, Н	
708	ASCLEPIAS TUBEROSA	A, H	
709	ASCOPHYLLUM NODOSUM	А, Е, Н	Iodine is a mandatory component of Ascophyllum nodosum.
			Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.
			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
710	ASCORBIC ACID	A, E	
711	ASCORBYL GLUCOSIDE	Ε	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 2%.
712	ASCORBYL METHYLSILANOL PECTINATE	Е	Only for use in topical medicines for dermal application.
713	ASCORBYL PALMITATE	Α, Ε	When for oral use, the maximum recommended daily dose must contain no more than 100mg of ascorbyl palmitate.

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Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020

Е

Only for use as an ingredient

ASCORBYL TOCOPHERYL

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	MALEATE		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%.
715	ASPALATHUS LINEARIS	A, E, H	
716	ASPARAGINE	A, E	
717	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%.
718	ASPARAGUS	E, H	Only for use as an active homoeopathic or excipient ingredient.
719	ASPARAGUS COCHINCHINENSIS	A, H	
720	ASPARAGUS OFFICINALIS	А, Е, Н	
721	ASPARAGUS RACEMOSUS	А, Н	The plant part must be dried, peeled root, and water extracts or ethanol/water extracts (containing up to 45% ethanol) of the dried, peeled root.
722	ASPARTAME	Е	When for oral use, the medicine requires the following warning statement on the medicine label:
			- (PKU) 'Phenylketonurics are warned that this product contains phenylalanine (or words to that effect)'
			The medicine requires the following warning statement on the medicine label:

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			- (ASPAR) 'Contains aspartame'
723	ASPARTIC ACID	A, E	
724	ASPERGILLUS ORYZAE	А, Е, Н	
725	ASTAXANTHIN ESTERS EXTRACTED FROM	А	Only for use in oral medicines.
	HAEMATOCOCCUS PLUVIALIS		Astaxanthin (of Haematococcus pluvialis) is a mandatory component of astaxanthin esters extracted from Haematococcus pluvialis.
			The maximum daily dose must contain no more than 12mg of Astaxanthin (of Haematococcus pluvialis).
726	ASTER TATARICUS	A, H	
727	ASTRAGALUS ADSURGENS	A, H	
728	ASTRAGALUS COMPLANATUS	A, H	
729	ASTRAGALUS EXCARPUS	A, H	
730	ASTRAGALUS GUMMIFER	А, Е, Н	
731	ASTRAGALUS LENTIGINOSUS	A, H	
732	ASTRAGALUS MEMBRANACEUS	А, Е, Н	
733	ASTRAGALUS PENDULIFLORUS	A, H	
734	ASTROCARYUM MURUMURU SEED TRIGLYCERIDES	Е	Only for use as an ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 0.21%.
735	ATRACTYLODES JAPONICA	A, H	
736	ATRACTYLODES LANCEA	A, H	
737	ATRACTYLODES MACROCEPHALA	А, Н	
738	ATROPA BELLADONNA	А, Н	Alkaloids calculated as hyoscyamine and atropine are

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	0		mandatory components of Atropa belladonna.
			The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.
			The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
739	ATROPINE SULFATE MONOHYDRATE	Н	Only for use as an active homoeopathic ingredient.
740	ATTALEA SPECIOSA	Е	Only for use in topical medicines for dermal application.
741	AURA B-AURANTIOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
742	AUREOBASIDIUM PULLULANS	A, H	
743	AVENA FATUA	А, Н	Gluten is a mandatory component of Avena fatua when the plant part is seed and the route of administration is other than topical and mucosal.
744	AVENA SATIVA	A, E, H	Gluten is a mandatory component of Avena sativa when the plant part is seed and the route of administration is other than topical and mucosal.

# Volume 1

	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
745	AVOCADO	E	
746	AVOCADO OIL	Е	
747	AVOCADO OIL UNSAPONIFIABLES	Е	Only for use in topical medicines for dermal application.
748	AZADIRACHTA INDICA	А, Н	The ingredient can only be derived from the plant part seed and must be cold pressed or debitterised oil.
			"Debitterised neem seed oil" means highly purified oil from the neem seed containing only fatty acids and glycerides of fatty acids.
			Cold pressed Azadirachta indica seed oil must be for topical use for dermal application only.
			When the concentration of cold pressed Azadirachta indica seed oil is more than 1%, a child resistant closure must be fitted to the container
			The medicine requires the following warning statements on the medicine label:
			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect).'
			- (NTAKEN) 'Not to be taken (or words to that effect).'
			- (CHILD) 'Keep out of reach of children (or words to that effect).'
749	AZOVAN BLUE	Е	Permitted for use only as a colour for topical use.
750	AZULENE	Е	Only for use in topical medicines for dermal

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Permissible in	ngredients and requirements		
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			application.
			application.