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

Note: See sections 5 and 6.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3618	P-ALPHA-DIMETHYL STYRENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3619	P-ANISIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
3620	PADIMATE O	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 8%. When used in primary sunscreen products, the following warning statements

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
3621	PADINA PAVONICA THALLUS PHYTOSTEROLS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
3622	PAEONIA LACTIFLORA	A, E, H	
3623	PAEONIA OBOVATA	A, H	
3624	PAEONIA SUFFRUTICOSA	A, E, H	
3625	PAEONIA VEITCHII	A, H	
3626	PALIURUS SPINA-CHRISTI	A, H	
3627	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3628	PALM FRUIT OIL	A, E, H	
3629	PALM GLYCERIDES	E	
3630	PALM KERNEL OIL	A, E, H	
3631	PALM TOCOTRIENOLS COMPLEX	A, H	
3632	PALMARIA PALMATA	A, H	
3633	PALMAROSA OIL	A, E, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3634	PALMIDROL	A	Only to be used in a medicine where Pharmako Biotechnologies Pty Ltd (Client ID 62358), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 02 December 2021. Only permitted for use in medicines limited to oral routes of administration. The maximum recommended daily dose of the medicine must not contain more than 600mg of palmidrol. The following warning statements are required on the medicine label: - 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use' (or words to that effect). - (ADULT) ‘Adults only’ (or words to that effect) - ‘Not to be used for more than 21 consecutive days’ (or words to that effect).
3635	PALMITIC ACID	E	
3636	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3637	PALMITOYL DIPEPTIDE-7	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 0.002%.
3638	PALMITOYL HYDROXYPROPYLTRIMONIUM AMYLOPECTIN/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%
3639	PALMITOYL OLIGOPEPTIDE	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 0.002%.
3640	PALMITOYL PENTAPEPTIDE-3	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 0.0005%.
3641	PALMITOYL TETRAPEPTIDE-3	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.001%.
3642	PANAX GINSENG	A, E, H	
3643	PANAX JAPONICUS	A, H	
3644	PANAX NOTOGINSENG	A, H	
3645	PANAX PSEUDOGINSENG	A, H	
3646	PANAX QUINQUEFOLIUS	A, H	
3647	PANICUM MILIACEUM	A, H	
3648	PANTETHINE	E	Only for use in topical medicines for dermal application.
3649	PANTHENOL	A, E	
3650	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3651	PANTOLACTONE	E	
3652	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3653	PANTOTHENIC ACID POLYPEPTIDE	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			0.1%.
3654	PAPAIN	A, E	
3655	PAPER	E	Only for use in topical medicines for dermal application.
3656	PAPRIKA OLEORESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3657	PARA-CRESOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3658	PARA-CRESYL 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
3659	PARA-CRESYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3660	PARA-CRESYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3661	PARA-CYMENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3662	PARA-ETHOXYBENZALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
3663	PARA-ETHYLPHENOL	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The maximum recommended daily dose must contain no more than 0.12 mg of para-ethylphenol. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
3664	PARA-HYDROXY BENZALACETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3665	PARA-HYDROXYBENZOIC ACID	E	
3666	PARA-MENTHA-8-THIOL-3-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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3667	PARA-METHYL ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3668	PARA-METHYL ANISOLE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3669	PARA-METHYL DIMETHYLBENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3670	PARA-PROPYL ANISOLE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3671	PARA-TERT-BUTYLCYCLOHEXYL 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%.
3672	PARA-TERT-BUTYLPHENYL-ALPHA-METHYLHYDROCINNAMIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3673	PARA-TOLUALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3674	PARA-TOLYL ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3675	PARAMERIA LAEVIGATA	A, H	
3676	PARIETARIA JUDAICA	A, H	
3677	PARIS POLYPHYLLA	A, H	
3678	PARIS QUADRIFOLIA	A, H	
3679	PARSLEY	E, H	
3680	PARSLEY HERB DRY	A, E, H	
3681	PARSLEY HERB OIL	A, E, H	
3682	PARSLEY HERB POWDER	A, E, H	
3683	PARSLEY SEED OIL	A, E, H	
3684	PARTHENOCISSUS TRICUSPIDATA	A, H	
3685	PARTIALLY HYDROGENATED SOYA 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 the medicine must be no more than 5%.
3686	PARTIALLY REFINED PORPHYRA YEZOENSIS CYTOPLASM EXTRACT	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			0.00002%.
3687	PASPALUM NOTATUM	A, H	
3688	PASSIFLORA CAERULEA	A, H	
3689	PASSIFLORA EDULIS	E	
3690	PASSIFLORA HERB DRY	A, H	
3691	PASSIFLORA INCARNATA	A, E, H	
3692	PATCHOULI 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%.
3693	PATENT BLUE V	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3694	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3695	PATRINIA SCABIOSIFOLIA	A, H	
3696	PATRINIA VILLOSA	A, H	
3697	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana. When the medicine is packaged for supply as an

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application, the medicine must not contain a concentration of total caffeine greater than 1%. c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
3698	PAULLINIA PINNATA	A, H	
3699	PAWPAW	E	
3700	PEA	E	
3701	PEA STARCH	E	
3702	PEACH	E	
3703	PEANUT	E	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
3704	PEAR	E	
3705	PECAN	E	
3706	PECTIN	A, E	
3707	PEG-10 DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must be no more than 4.0%.
3708	PEG-10 SOYA STEROL	E	Only for use in topical

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines for dermal application.
3709	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3710	PEG-12 DILAURATE	E	
3711	PEG-12 DIMETICONE/PPG-20 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3712	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3713	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3714	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3715	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3716	PEG-20 ALMOND GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3717	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3718	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3719	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3720	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3721	PEG-25 PABA	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3722	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3723	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3724	PEG-35 CASTOR OIL	E	
3725	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3726	PEG-4 LAURATE	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of PEG-4 laurate. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3727	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3728	PEG-40 CASTOR OIL	E	
3729	PEG-40 HYDROGENATED CASTOR OIL	E	
3730	PEG-40 SORBITAN DIISOSTEARATE	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of PEG-40 sorbitan diisostearate. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3731	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3732	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3733	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3734	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3735	PEG-55 PROPYLENE GLYCOL OLEATE	E	Only for use in topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.6%.
3736	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3737	PEG-60 ALMOND GLYCERIDES	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 when used in medicines applied directly to the skin must be no more than 10%. The concentration when used in bath oil medicines must be no more than 30%.
3738	PEG-60 GLYCERYL ISOSTEARATE	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%.
3739	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3740	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3741	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3742	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3743	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3744	PEG-75 STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3745	PEG-8 CETYL DIMETHICONE	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 0.0005%.
3746	PEG-8 DILAURATE	E	Only for use in topical medicines for dermal application and not to be

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
3747	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3748	PEG-8 LAURATE	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 4%. The levels of possible impurities such as ethylene oxide (and related material) must be kept below the level of detection.
3749	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3750	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3751	PEG-9 POLYDIMETHYLSILOXYETHYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.5%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3752	PEG/PPG-14/7 DIMETHYL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 7%.
3753	PEG/PPG-18/18 DIMETHICONE	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%.
3754	PELARGONIUM GRAVEOLENS	A, E, H	
3755	PELLITORINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3756	PELTIGERA CANINA	A, H	
3757	PENICILLIUM EXPANSUM	A, H	
3758	PENNYROYAL OIL	E	D-Pulegone/Pulegone is a mandatory component of Pennyroyal Oil. The concentration of D Pulegone/ Pulegone in the medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			4%. Permitted for use only in combination with other permitted ingredients as a flavour or a 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 the medicine must be no more than 1%. When the medicine is for a use other than topical, the maximum recommended daily dose must be no more than 50 mg of Pennyroyal Oil.
3759	PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE	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 0.018%
3760	PENTAERYTHRITYL TETRAISOSTEARATE	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 61%.
3761	PENTAERYTHRITYL	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	TETRALAURATE		application. The concentration in the medicine must be no more than 80%.
3762	PENTAMETHYLHEPTENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3763	PENTANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3764	PENTASODIUM ETHYLENEDIAMINE TETRAMETHYLENE PHOSPHONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3765	PENTYLENE GLYCOL	E	Only for use in topical medicines for dermal application and not to be

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3766	PEPPER BLACK	E, H	
3767	PEPPER OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3768	PEPPER WHITE	E, H	
3769	PEPPERMINT AMERICAN EXT.	E	Menthol is a mandatory component of peppermint american ext. When the medicine is for topical use for dermal application: a) the medicine must not be intended for use in the eye or on damaged skin; b) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; c) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). d) if the medicine delivers more than 1% total menthol

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. e) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3770	PEPPERMINT LEAF DRY	A, E, H	Menthol is a mandatory component of peppermint leaf dry. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3771	PEPPERMINT LEAF POWDER	A, E, H	Menthol is a mandatory component of peppermint leaf powder. When the medicine is for

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			recommended daily dose must not contain more than 1 gram of menthol.
3772	PEPPERMINT OIL	A, E, H	Menthol is a mandatory component of peppermint oil. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3773	PEPPERMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. The total fragrance proprietary excipient formulation in a medicine must be no more 1%. Menthol is a mandatory component of peppermint oil terpeneless. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3774	PEPPERMINT OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. Menthol is a mandatory component of peppermint oil terpenes and terpenoids. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol when administered according

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3775	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3776	PERHYDRO-3,6-DIMETHYL-BENZO [B] FURAN-2-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%.
3777	PERILLA FRUTESCENS	A, E, H	Rosmarinic acid and vicenin-2 are only permitted for use if the plant part of Perilla frutescens is leaf.
3778	PERILLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3779	PERLITE	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%.
3780	PERMETHRIN	E	The concentration of in the medicine must be no more than 2%.
3781	PERSEA AMERICANA	A, E, H	
3782	PERSIC OIL	A, E, H	Amygdalin and Hydrocyanic acid are mandatory components of Persic oil. The concentration of amygdalin in the medicine must be no more than 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
3783	PERSICARIA CHINENSIS	A, H	
3784	PERSICARIA TINCTORIA	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3785	PERSIMMON	E	
3786	PERU BALSAM	A, E, H	
3787	PERU BALSAM OIL	A, E, H	
3788	PETITGRAIN MANDARIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour The final concentration of the oil in the flavour does not exceed 30% If used in a flavour the total flavour concentration in a medicine must be no more than 5%
3789	PETITGRAIN 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%.
3790	PETITGRAIN OIL CITRONNIER	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. When included in a medicine for use on the lips the concentration of petitgrain oil citronnier must be no more than 0.1%. When included in dermal

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			creams for infant use the concentration of petitgrain oil citronnier must be no more than 0.5% The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3791	PETITGRAIN OIL PARAGUAY	A, E, H	When used internally, oxedrine is a mandatory component of petitgrain oil paraguay. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3792	PETITGRAIN OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3793	PETROSELINUM CRISPUM	A, E, H	
3794	PEUCEDANUM PRAERUPTORUM	A, E, H	
3795	PEUMUS BOLDUS	A, H	Volatile oil components (of Peumus boldus) is a mandatory component. The maximum recommended daily dose must be no more than 100 mg of volatile oil components (of Peumus

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			boldus).
3796	PHALARIS ARUNDINACEA	A, H	
3797	PHALARIS CANARIENSIS	A, H	
3798	PHASEOLUS COCCINEUS	A, H	
3799	PHASEOLUS VULGARIS	A, H	
3800	PHELLINUS ROBINIAE	A, E, H	
3801	PHELLODENDRON AMURENSE	A, E, H	
3802	PHELLODENDRON CHINENSE	A, H	
3803	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3804	PHENETHYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3805	PHENETHYL 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3806	PHENETHYL ALCOHOL	E	Permitted for use only: a) in topical medicines for dermal application; and b) for internal use in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation concentration in a medicine must be no more than 5%.
3807	PHENETHYL BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3808	PHENETHYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%
3809	PHENETHYL ISOAMYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3810	PHENETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3811	PHENETHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3812	PHENETHYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients 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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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3813	PHENETHYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3814	PHENOL	E	Only for use in topical medicines for dermal application. The concentration of phenol in the medicine must be no more than 1%.
3815	PHENOXYACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3816	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The concentration of phenoxyethanol in the preparation must not exceed

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			15%.
3817	PHENOXYETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3818	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
3819	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3820	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3821	PHENYLACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
3822	PHENYLACETALDEHYDE DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3823	PHENYLACETALDEHYDE GLYCERYLACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3824	PHENYLACETIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3825	PHENYLALANINE	A, E	When for oral ingestion the medicine requires the following warning statement

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			on the medicine label: - (PKU) 'Phenylketonurics are warned that this medicine contains phenylalanine' (or words to that effect). When the medicine contains more than 500mg in the maximum recommended daily dose it requires the following warning statement on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.
3826	PHENYLBENZIMIDAZOLE SULFONIC ACID	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 4%. When used in primary sunscreen products, 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).
3827	PHENYLETHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3828	PHENYLETHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3829	PHENYLETHYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3830	PHENYLETHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3831	PHENYLETHYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3832	PHENYLETHYL METHYLETHYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3833	PHENYLETHYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
3834	PHENYLETHYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
3835	PHENYLISOPROPYL DIMETICONE	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%.
3836	PHENYLPROPANOL	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 0.16%.
3837	PHLEUM PRATENSE	A, H	
3838	PHLOXINE B	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3839	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3840	PHOENIX DACTYLIFERA	A, E, H	
3841	PHOSPHATIDYL CHOLINE	E	
3842	PHOSPHOLIPIDS	E	Only for use in topical medicines for dermal application and not intended

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 20%.
3843	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3844	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient.
3845	PHOTINIA SERRULATA	A, H	
3846	PHRAGMITES AUSTRALIS	A, H	
3847	PHYLLANTHUS AMARUS	A, H	
3848	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application. When ascorbic acid is claimed as a component the plant part is restricted to fruit.
3849	PHYLLOSTACHYS NIGRA	A, E, H	
3850	PHYSALIS ALKEKENGI	A, H	
3851	PHYSALIS PUBESCENS	A, H	
3852	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3853	PHYTOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3854	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3855	PHYTOMENADIONE	A, E	
3856	PHYTOSPHINGOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3857	PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3858	PICEA ABIES	A, H	
3859	PICEA MARIANA	A, H	
3860	PICRASMA EXCELSA	A, E, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3861	PICRORRHIZA KURROA	A, E, H	
3862	PIGMENT BLUE 15	E	Permitted for use only as a colour for topical and dental use. The concentration in medicine must be no more than 0.003%.
3863	PIGMENT BLUE 15:1	E	Permitted for use only as a colour for topical use. 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 0.21%.
3864	PIGMENT GREEN 7	E	Permitted for use only as a colour for topical and dental use. When for dental use, the concentration in the medicine must be no more than 0.003%. When for topical use, the concentration in the medicine must be no more than 0.17%.
3865	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3866	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3867	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3868	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3869	PIGMENT RED 57 BARIUM LAKE	E	Permitted for excipient use as a colour in topical medicines for dermal application. Not to be included in medicines intended for use in the eye.
3870	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3871	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3872	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.
3873	PILOCARPUS JABORANDI	A, H	Pilocarpine is a mandatory component of Pilocarpus jaborandi. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3874	PILOCARPUS MICROPHYLLUS	A, H	Pilocarpine is a mandatory component of Pilocarpus microphyllus. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3875	PILOCARPUS PINNATIFOLIUS	A, H	Pilocarpine is a mandatory component of Pilocarpus

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			pinnatifolius. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3876	PIMENTA FRUIT OIL	A, E, H	
3877	PIMENTA LEAF OIL	A, E, H	
3878	PIMENTA OFFICINALIS	A, E, H	
3879	PIMENTA RACEMOSA	A, E, H	When the plant preparation for Pimenta racemosa is an oil and the concentration of this oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL, a restricted flow insert must be fitted on the container. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect)

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (NTAKEN) 'Not to be taken'.
3880	PIMPINELLA ANISUM	A, E, H	When the plant preparation for Pimpinella anisum is an oil or distillate and the concentration of this oil or distillate in the medicine is more than 50%: a) the nominal capacity of the container must be no more than 50 millilitres; and b) a restricted flow insert is must be fitted on the container; and c) the medicine requires the following warning statement on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or words to that effect).
3881	PIMPINELLA SAXIFRAGA	A, E, H	
3882	PINE NEEDLE OIL SCOTCH	A, E, H	
3883	PINE NEEDLE OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
3884	PINE OIL AROMATIC	A, E, H	
3885	PINE OIL PUMILIO	A, E, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3886	PINEAPPLE	E	
3887	PINEAPPLE OILS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3888	PINELLIA TERNATA	A, H	
3889	PINUS CONTORTA	A, E, H	
3890	PINUS ELLIOTTII	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
3891	PINUS MASSONIANA	A, E, H	When the plant preparation is oil or distillate the total concentration of Pinus massoniana oil or distillate in the preparation must be no more than 25%.
3892	PINUS MONTICOLA	A, E, H	
3893	PINUS MUGO	A, E, H	
3894	PINUS PALUSTRIS	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%.
3895	PINUS PINASTER	A, E, H	When the plant preparation is oil or distillate the total concentration of Pinus pinaster oil or distillate in the preparation must be no more than 25%.
3896	PINUS PONDEROSA	A, E, H	
3897	PINUS RADIATA	A, E, H	
3898	PINUS STROBUS	A, E, H	
3899	PINUS SYLVESTRIS	A, E, H	
3900	PINUS TABULIFORMIS	A, E, H	
3901	PINUS YUNNANENSIS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3902	PIPENZOLATE BROMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3903	PIPER CHABA	A, E, H	
3904	PIPER CUBEBA	A, E, H	
3905	PIPER KADSURA	A, E, H	
3906	PIPER LONGUM	A, E, H	
3907	PIPER METHYSTICUM	A, H	Kavalactones (of Piper methysticum) is a mandatory component of Piper methysticum. Only for oral use when the dosage form is 'tablet' or 'capsule'; or when the container type is 'tea bag'. When used in oral medicines, the maximum daily dose of kavalactones (of Piper methysticum) must be no more than 250 mg. If the dosage form is tablet or capsule then the quantity of kavalactones (of Piper methysticum) must be no more than 125 mg per tablet or capsule. Oral medicines containing more than 25 mg of kavalactones (of Piper methysticum) per dose require the following warning statement on the medicine label: - (PIPER) 'Not for prolonged use. If symptoms persist - seek advice from a healthcare practitioner. Not recommended for pregnant or lactating women (or words to that effect). May harm the liver'.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The plant part must be root or rhizome. When for oral use, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome. When for topical use on the rectum, vagina or throat, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome. When the container type is tea bag the maximum quantity per tea bag must be no more than 3 grams of dried whole or peeled root or rhizomes.
3908	PIPER NIGRUM	A, E, H	
3909	PIPER SARMENTOSUM	A, E, H	
3910	PIPERIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3911	PIPERINE	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary formulation. The total flavour proprietary formulation in a medicine must

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			not be more than 5% and the concentration of piperine in the medicine must not be more than 0.15%.
3912	PIPERITONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3913	PIPERONAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3914	PIPERONYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3915	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (PIPBUT) 'Contains piperonyl butoxide' (or words to that effect).
3916	PIROCTONE OLAMINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1% in wash-on/wash-off medicines and 0.5% in leave-on medicines.
3917	PISCIDIA PISCIPULA	A, E, H	
3918	PISTACIA LENTISCUS	A, E, H	
3919	PISUM SATIVUM	A, E, H	
3920	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3921	PLANTAGO AFRA	A, E, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			(a) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3922	PLANTAGO ARENARIA	A, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When a dose for children is stated and the plant part is flower, seed or pollen, the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL) 'On medical advice' (or words to that effect).
3923	PLANTAGO ASIATICA	A, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			used for children on medical advice' (or words to that effect). The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3924	PLANTAGO LANCEOLATA	A, E, H	The medicine requires the following warning statement on the medicine label: - (CHILD5) 'Use in children under 3 years is not recommended' The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When a dose for children is stated and the plant part is flower, seed or pollen, the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL) 'On medical advice' (or words to that effect).
3925	PLANTAGO MAJOR	A, E, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			used for children on medical advice' (or words to that effect). The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL) 'On medical advice' (or words to that effect).
3926	PLANTAGO OVATA	A, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3927	PLANTAGO SEED DRY	A, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). The requirement specified in paragraph (b) below applies in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) 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).
3928	PLATANUS OCCIDENTALIS	A, E, H	
3929	PLATANUS RACEMOSA	A, H	
3930	PLATANUS X ACERIFOLIA	A, H	
3931	PLATYCODON GRANDIFLORUS	A, E, H	
3932	PLECTRANTHUS BARBATUS	A, E, H	
3933	PLICATONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3934	PLUM	E	
3935	PLUMBAGO EUROPAEA	A, H	
3936	PLUMERIA ALBA	A, E, H	
3937	PLUMERIA RUBRA	A, E, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3938	POA NEMORALIS	A, H	
3939	POA PRATENSIS	A, H	
3940	PODOPHYLLUM PELTATUM	A, H	Podophyllin and podophyllotoxin are mandatory components of Podophyllum peltatum. The concentration of podophyllin in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%. The concentration of podophyllotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3941	POGOSTEMON CABLIN	A, E, H	
3942	POLACRILIN	E	
3943	POLACRILIN POTASSIUM	E	
3944	POLAPREZINC	A	Only for use in oral medicines. Zinc is a mandatory component of Polaprezinc. The maximum recommended daily dose must be no more than 34 milligrams of zinc sourced from polaprezinc. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect).
3945	POLIGLUSAM	A, E	The average molecular mass of poliglusam must be greater than 2 kilodaltons. When for internal use, the medicine must not contain more than 1750 milligrams of poliglusam per maximum recommended daily dose. When for internal use, the following warning statements are required on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect); and - (SFOOD) 'Derived from seafood'. When for internal use and the dosage form is a powdered preparation, the medicine requires the following warning statements on the medicine label: - (DNTPOW) 'Do not take powder alone. Mix with food or fluid'. When used as an excipient, only for use in topical

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines for dermal application.
3946	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	When for oral use, the medicine must provide no more than 2000 milligrams of Poliglusam derived from Aspergillus niger per maximum recommended daily dose and requires the following warning statement on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect). If the medicine is a powdered dosage form, the medicine also requires the following warning statement on the medicine label: - 'Do not take powder alone. Mix with food or fluid.' When used as an excipient, Poliglusam derived from Aspergillus niger is only permitted for use in topical medicines for dermal application.
3947	POLLACK-LIVER OIL	A, E	Colecalciferol and Vitamin A are mandatory components of Pollack-liver oil. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3948	POLLEN	E	The medicine requires the following warning statement on the medicine label: - (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect).
3949	POLOXAMER	E	Only for use in topical medicines for dermal application.
3950	POLOXAMINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3951	POLOXAMINE 1301	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3952	POLY C10-30 ALKYL ACRYLATE	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			2%.
3953	POLYACRYLAMIDE	E	Only for use in topical medicines for dermal application. Acrylamide is a mandatory component of Polyacrylamide. The concentration of Acrylamide in the medicine must be no more than 0.01%.
3954	POLYACRYLATE CROSSPOLYMER-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3955	POLYACRYLATE-1 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.4%.
3956	POLYACRYLIC ACID	E	
3957	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3958	POLYAMINOPROPYL	E	Only for use in topical

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	BIGUANIDE		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 0.3%.
3959	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3960	POLYBUTYLENE GLYCOL/PPG-9/1 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%.
3961	POLYCAPROLACTONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3962	POLYDECENE	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 6%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3963	POLYDEXTROSE	E	
3964	POLYDIETHYLSILOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
3965	POLYDIMETHYL SILOXANE	E	Permitted for use only in combination with other permitted ingredients as a printing ink. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
3966	POLYESTER-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3967	POLYESTER-25	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3968	POLYESTER-7	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%.
3969	POLYESTER-8	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 of Polyester-8 must be no more than 5%.
3970	POLYETHYLENE	E	
3971	POLYGALA CHINENSIS	A, H	
3972	POLYGALA SENEGA	A, E, H	Except when used in a medicine containing only homoeopathic preparations, a child resistant closure and restricted flow insert must be fitted onto the container.
3973	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
3974	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
3975	POLYGLYCERYL-10 PENTASTEARATE	E	Only for use in topical medicines for dermal application and not to be

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3976	POLYGLYCERYL-2 CAPRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. The concentration in the medicine must not be more than 0.5%.
3977	POLYGLYCERYL-2 DIISOSTEARATE	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 3.0%.
3978	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3979	POLYGLYCERYL-2 DISTEARATE	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must not be more than 3%.
3980	POLYGLYCERYL-2 TRIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When the concentration of polyglyceryl-2 triisostearate is greater than 3%, the medicine must not be intended for use on damaged skin. The concentration in the medicine must not be more than 5%.
3981	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3982	POLYGLYCERYL-3 BEESWAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.
3983	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
3984	POLYGLYCERYL-3 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 0.5%.
3985	POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE	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 6%.
3986	POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE	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 5.5%.
3987	POLYGLYCERYL-3 POLYRICINOLEATE	E	
3988	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIMER DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
3989	POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE	E	Only for use in topical medicines for dermal application and not to be

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
3990	POLYGLYCERYL-4 ISOSTEARATE	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%.
3991	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
3992	POLYGLYCERYL-6 POLYRICINOLEATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
3993	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
3994	POLYGONATUM MULTIFLORUM	A, H	
3995	POLYGONATUM OFFICINALE	A, H	
3996	POLYGONATUM SIBIRICUM	A, E, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3997	POLYGONUM AVICULARE	A, E, H	When used as an excipient, the medicine is 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. When used as an excipient, the concentration in the medicine must be no more than 0.16%.
3998	POLYGONUM BISTORTA	A, H	
3999	POLYGONUM ODORATUM	A, H	
4000	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
4001	POLYISOBUTYLENE	E	Only for use when the dosage form is 'chewing gum'. Must comply with: a) the Polyisobutylene monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia National Formulary, as in force or existing from time to time.
4002	POLYISOPRENE	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4003	POLYLIMONENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4004	POLYMETHACRYLIC ACID	E	
4005	POLYMETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
4006	POLYMETHYLSILSESQUIOXANE	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 3%.
4007	POLYPORUS UMBELLATUS	A, H	
4008	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
4009	POLYPROPYLENE GLYCOL	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
4010	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
4011	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4012	POLYQUATERNIUM-22	E	Only for use in wash-off 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 2%.
4013	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
4014	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
4015	POLYQUATERNIUM-37	E	Only for use in topical medicines for dermal application and not to be

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4016	POLYQUATERNIUM-4	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 not be more than 0.4%.
4017	POLYQUATERNIUM-44	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 0.3%.
4018	POLYQUATERNIUM-51	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%.
4019	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4020	POLYSILICONE-11	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 2.1%
4021	POLYSILICONE-14	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 of Polysilicone-14 must be no more than 1%.
4022	POLYSILICONE-15	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, 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).

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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4023	POLYSILICONE-2	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 0.13%.
4024	POLYSORBATE 20	E	
4025	POLYSORBATE 40	E	
4026	POLYSORBATE 60	E	
4027	POLYSORBATE 65	E	
4028	POLYSORBATE 80	E	
4029	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4030	POLYTEF	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4031	POLYURETHANE-34	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% in spray applications and

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			6% in non-spray applications.
4032	POLYURETHANE-62	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4033	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4034	POLYVINYL ACETATE PHTHALATE	E	
4035	POLYVINYL ALCOHOL	E	
4036	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4037	POMEGRANATE	E	
4038	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4039	PONCIRUS TRIFOLIATA	A, H	When used internally, oxedrine is a mandatory component of Poncirus trifoliata. The quantity of Oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4040	PONGAMOL	E	Only for use in topical medicines for dermal application and not to be

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4041	POPPY SEED	E, H	
4042	POPPY SEED OIL	E, H	
4043	POPULUS ALBA	A, H	
4044	POPULUS BALSAMIIFERA	A, E, H	
4045	POPULUS CANDICANS	A, H	
4046	POPULUS DELTOIDES	A, H	
4047	POPULUS NIGRA	A, H	
4048	POPULUS TREMULA	A, H	
4049	POPULUS TREMULOIDES	A, H	
4050	PORCINE	H	Only for use as an active homoeopathic ingredient.
4051	PORPHYRIDIUM PURPUREUM EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4052	PORTULACA OLERACEA	A, E, H	
4053	POTABLE WATER	E	
4054	POTASSIUM ACETATE	E	
4055	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4056	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4057	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4058	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4059	POTASSIUM ASPARTATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium aspartate.
4060	POTASSIUM ASPARTATE DIHYDRATE	A, E, H	If used as an active ingredient and the preparation is intended as a mineral supplementation, potassium is a mandatory component of Potassium aspartate dihydrate. The percentage of potassium from potassium aspartate dihydrate should be calculated based on the molecular weight of potassium aspartate dihydrate.
4061	POTASSIUM ASPARTATE MONOHYDRATE	A, E	If used as an active ingredient and the preparation is intended as a mineral supplementation, potassium is a mandatory component of Potassium

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			aspartate monohydrate. The percentage of potassium from potassium aspartate monohydrate should be calculated based on the molecular weight of potassium aspartate monohydrate.
4062	POTASSIUM BICARBONATE	E	
4063	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4064	POTASSIUM CARBONATE	E, H	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4065	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4066	POTASSIUM CHLORIDE	A, E, H	When for oral use: a) potassium is a mandatory component of potassium chloride; b) the medicine requires the following warning statement on the medicine label: - (POTAS) 'Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			out of reach of children.'; and c) other than when used for oral rehydration therapy, the concentration must be no more than 550 mg per dosage unit. Medicines for use as oral rehydration therapy, are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and c) the medicine requires the warning statements: - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration in the medicine must be no more than 3.75%.
4067	POTASSIUM CITRATE	A, E, H	When used as an active ingredient and the medicine is

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			intended as a mineral supplementation, potassium is a mandatory component of potassium citrate.
4068	POTASSIUM COCOYL HYDROLYSED COLLAGEN	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 10%.
4069	POTASSIUM COCOYL HYDROLYSED SOY PROTEIN	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 0.15%.
4070	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4071	POTASSIUM GLUCONATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium gluconate.
4072	POTASSIUM GLYCEROPHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			a mandatory component of potassium glycerophosphate.
4073	POTASSIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4074	POTASSIUM HYDROXYCITRATE	A, H	
4075	POTASSIUM IODATE	A, H	Iodine is a mandatory component of potassium iodate. The percentage of iodine from potassium iodate should be calculated based on the molecular weight of potassium iodate. When for use in adults, the medicine must contain a daily dose of no more than 505 micrograms of potassium iodate. When for use in children aged 1-3 years, the medicine must contain a daily dose of no more than 337 micrograms of potassium iodate.
4076	POTASSIUM IODIDE	A, E, H	Iodine is a mandatory component of potassium iodide.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The percentage of iodine from potassium iodide should be calculated based on the molecular weight of potassium iodide. When for internal use, the maximum recommended daily dose of the medicine must contains less than 300 micrograms of iodine. When for external use, the concentration of iodine in the medicine (excluding salts derivatives or iodophors) must not exceed 2.5%.
4077	POTASSIUM METABISULFITE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4078	POTASSIUM METAPHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4079	POTASSIUM NITRATE	A, H	Only for dental use. The concentration in the medicine must be no more than 5%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4080	POTASSIUM OROTATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium orotate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4081	POTASSIUM PYROPHOSPHATE	E	Only for oral application, dental or topical use. Not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4082	POTASSIUM SORBATE	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4083	POTASSIUM STANNATE	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4084	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4085	POTASSIUM SULFATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium sulfate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4086	POTATO STARCH	E	
4087	POTENTILLA ANSERINA	A, H	
4088	POTENTILLA CHINENSIS	A, H	
4089	POTENTILLA DISCOLOR	A, H	
4090	POTENTILLA ERECTA	A, E, H	
4091	POTENTILLA REPTANS	A, H	
4092	POTERIUM OFFICINALE	A, E, H	
4093	POTERIUM SANGUISORBA	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4094	POVIDONE	E	
4095	POWDERED CELLULOSE	E	
4096	PPG-1-PEG-9 LAURYL GLYCOL ETHER	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%.
4097	PPG-12/SMDI 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%.
4098	PPG-15 STEARYL ETHER	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 4%.
4099	PPG-15 STEARYL ETHER BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.4%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4100	PPG-17/IPDI/DMPA 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 or on damaged skin. The concentration of PPG-17/IPDI/DMPA Copolymer in the medicine must be no more than 10%.
4101	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4102	PPG-2 MYRISTYL ETHER PROPIONATE	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%.
4103	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4104	PPG-20 METHYL GLUCOSE ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4105	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4106	PPG-3 HYDROGENATED CASTOR OIL	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 6%.
4107	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4108	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4109	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4110	PRALINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4111	PREGELATINISED MAIZE STARCH	E	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4112	PREGELATINISED POTATO STARCH	E	
4113	PREGELATINISED RICE STARCH	E	
4114	PREGELATINISED STARCH	E	
4115	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4116	PRENYL 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%.
4117	PRICKLY ASH BARK DRY	A, H	
4118	PRICKLY ASH BARK POWDER	A, H	
4119	PRIMULA VERIS	A, E, H	
4120	PRIMULA VULGARIS	A, E, H	
4121	PRINSEPIA UNIFLORA	A, H	
4122	PROBOSCIDEA PARVIFLORA	A, H	
4123	PROGESTERONE	H	Only for use as an active homoeopathic ingredient.
4124	PROLINE	A, E	
4125	PROPAN-1-OL	E	Only for use in: - topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application; or - in combination with other permitted ingredients as a flavour proprietary excipient formulation. The concentration of propan-1-ol in the medicine must not be more than 18%. When used in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation, the total flavour proprietary excipient formulation in a medicine must not be more than 5%.
4126	PROPANE	E	Only for use as an excipient propellant ingredient.
4127	PROPANEDIOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%.
4128	PROPENYL GUAETHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more 1%.
4129	PROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4130	PROPIONIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4131	PROPIONYLLEVOCARNITINE HYDROCHLORIDE	A, H	
4132	PROPOLIS	A, E	Lead is a mandatory component of Propolis. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING:

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4133	PROPOLIS BALSAM	A, E	Lead is a mandatory component of Propolis balsam. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4134	PROPOLIS DRY EXTRACT	A, E	Lead is a mandatory component of Propolis dry extract.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4135	PROPOLIS LIQUID EXTRACT	A, E	Lead is a mandatory component of Propolis liquid extract. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label:

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4136	PROPOLIS RESIN	A, E	Lead is a mandatory component of propolis resin. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4137	PROPOLIS TINCTURE	A, E	Lead is a mandatory component of Propolis tincture. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING:

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4138	PROPYL 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%.
4139	PROPYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4140	PROPYL GALLATE	E	
4141	PROPYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4142	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4143	PROPYLENE GLYCOL	E	
4144	PROPYLENE GLYCOL ALGINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4145	PROPYLENE GLYCOL DIBENZOATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 20%.
4146	PROPYLENE GLYCOL DIDECANOATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1%.
4147	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4148	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4149	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4150	PROPYLENE GLYCOL ISOCETETH-3 ACETATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4151	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4152	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4153	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4154	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4155	PROSOPIS JULIFLORA	A, H	
4156	PROTEASE	A	Must be derived from Aspergillus oryzae or Aspergillus niger. When the dosage form is undivided, the units 'haemoglobin unit on the tyrosine basis per gram' and 'Thousand haemoglobin units on the tyrosine basis per gram' are permitted. When the dosage form is divided, the units 'haemoglobin units on the tyrosine basis' and 'thousand haemoglobin units on the tyrosine basis' are permitted.
4157	PROTEIN HYDROLYSATE	E	
4158	PRUNE JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4159	PRUNE JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
4160	PRUNELLA VULGARIS	A, H	
4161	PRUNUS AFRICANA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus africana. 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%.
4162	PRUNUS ARMENIACA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus armeniaca and must be declared in the application. 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%.
4163	PRUNUS AVIUM	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus avium. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4164	PRUNUS CERASIFERA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera. 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%.
4165	PRUNUS CERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasus. 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%.
4166	PRUNUS DOMESTICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1 microgram/kg or 1 microgram/L or 0.0000001%.
4167	PRUNUS DULCIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus dulcis when the plant part is seed. When the plant part is seed, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry seed. 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%.
4168	PRUNUS HUMILIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus humilis. 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%.
4169	PRUNUS JAPONICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus japonica. The concentration of Amygdalin in the medicine

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
4170	PRUNUS LAUROCERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus. 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%.
4171	PRUNUS MUME	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus mume. 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%.
4172	PRUNUS PERSICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus persica. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4173	PRUNUS SALICINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina. 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%.
4174	PRUNUS SEROTINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus serotina. 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%.
4175	PRUNUS SPINOSA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa. 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			microgram/L or 0.0000001%.
4176	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4177	PSEUDOCYDONIA SINENSIS	A, H	
4178	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4179	PSEUDOTSUGA MENZIESII	A, H	
4180	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4181	PSIDIUM GUAJAVA	A, E, H	
4182	PSORALEN (OF CULLEN CORYLIFOLIUM)	E	
4183	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4184	PSYLLIUM HUSK DRY	A, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). The requirement specified in

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated, the following warning statement is required on medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4185	PSYLLIUM HUSK POWDER	A, E, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. (b) When a dose for children is stated, the following warning statement is required on the label: - (PSYLL) 'On medical advice' (or words to that effect).
4186	PSYLLIUM SEED DRY	A, E, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When a dose for children is stated the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that: - is listed in the Register before 2 March 2020; and - is supplied before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			(b) When a dose for children is stated, the following warning statement is required on the label: - (PSYLL) 'On medical advice' (or words to that effect).
4187	PTELEA TRIFOLIATA	A, H	
4188	PTEROCARPUS MARSUPIUM	A, H	
4189	PTEROCARPUS SANTALINUS	A, E, H	
4190	PUERARIA LOBATA	A, E, H	
4191	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4192	PULLULAN	E	
4193	PUMICE	E	
4194	PUMPKIN	E	
4195	PUMPKIN SEED	E, H	
4196	PUMPKIN SEED OIL	E, H	
4197	PUNICA GRANATUM	A, E, H	
4198	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4199	PURIFIED HONEY	A, E	When the route of administration is oral, the medicine requires the following warning statement on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4200	PURIFIED SILICEOUS EARTH	E, H	
4201	PURIFIED TALC	E	
4202	PURIFIED WATER	E	
4203	PVM/MA COPOLYMER	E	
4204	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4205	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4206	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4207	PYRETHRINS	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%. The medicine requires the following warning statement on the medicine label: - (PYRTH3) 'Contains pyrethrins [insert quantity]' (or words to that effect).
4208	PYRIDOXAL 5-PHOSPHATE	A, E	Pyridoxine is a mandatory component of Pyridoxal 5-phosphate. The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			vitamin B6].'
4209	PYRIDOXAL 5-PHOSPHATE MONOHYDRATE	A	Pyridoxine is a mandatory component of Pyridoxal 5-phosphate monohydrate. The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
4210	PYRIDOXINE HYDROCHLORIDE	A, E, H	When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of Pyridoxine hydrochloride. The percentage of pyridoxine from pyridoxine hydrochloride should be calculated based on the molecular weight of

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			pyridoxine hydrochloride. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
4211	PYROGLUTAMIC ACID	E	
4212	PYROLA DECORATA	A, H	
4213	PYROLIGNEOUS ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4214	PYRROSIA LINGUA	A, H	
4215	PYRROSIA PETIOLOSA	A, H	
4216	PYRROSIA SHEARERI	A, H	
4217	PYRUS COMMUNIS	A, E, H	Arbutin is a mandatory component of Pyrus communis.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
4218	PYRUS PYRIFOLIA	A, H	Arbutin is a mandatory component of Pyrus pyrifolia. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
4219	PYRUVIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4220	QUASSIA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
4221	QUASSIA AMARA	A, E, H	
4222	QUASSIA WOOD JAMAICAN DRY	A, H	
4223	QUASSIA WOOD JAMAICAN POWDER	A, H	
4224	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4225	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4226	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4227	QUATERNIUM-52	E	Only for use in wash-on/wash-off 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%. Not be used in medicines in which N-nitroso compounds may be formed.
4228	QUATERNIUM-80	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			2.5%.
4229	QUERCETIN	A	
4230	QUERCETIN DIHYDRATE	A	
4231	QUERCUS ACUTISSIMA	A, H	
4232	QUERCUS ALBA	A, E, H	
4233	QUERCUS PALUSTRIS	A, H	
4234	QUERCUS ROBUR	A, H	
4235	QUERCUS RUBRA	A, H	
4236	QUERCUS VIRGINIANA	A, H	
4237	QUILLAIA DRY	A, H	
4238	QUILLAIA POWDER	A, E, H	
4239	QUILLAJA SAPONARIA	A, H	
4240	QUINCE	E	
4241	QUININE ARSENITE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of Quinine arsenite. The maximum recommended daily dose must be no more than 50 mg of quinine.
4242	QUININE SULFATE DIHYDRATE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of quinine sulfate dihydrate. The maximum recommended daily dose must be no more than 50 mg of quinine.
4243	QUINOLINE YELLOW	E	Permitted for use only as a

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			colour for oral and topical use.
4244	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4245	QUISQUALIS INDICA	A, H	
4246	R-ALPHA LIPOIC ACID	A	
4247	RACEMENTHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
4248	RACEMIC CAMPHOR	E, H	Only for use as an active homoeopathic or excipient ingredient. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
4249	RADISH	E	
4250	RAISIN JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4251	RANUNCULUS BULBOSUS	A, H	
4252	RANUNCULUS FICARIA	A, H	
4253	RANUNCULUS TERNATUS	A, H	
4254	RAPE SEED OIL	A, E, H	Allyl isothiocyanate is a mandatory component of rape seed oil when the plant part is seed. 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%.
4255	RAPHANUS SATIVUS	A, H	
4256	RASPBERRY	E	
4257	RASPBERRY BRANDY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
4258	RASPBERRY DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4259	RASPBERRY ESSENCE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4260	RASPBERRY JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4261	RAUWOLFIA SERPENTINA	A, H	The concentration of equivalent dry Rauwolfia serpentina in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4262	RAUWOLFIA SERPENTINA DRY	A, H	The concentration of Rauwolfia Serpentina Dry in

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4263	RAUWOLFIA SERPENTINA POWDER	A, H	The concentration of Rauwolfia Serpentina Powder in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4264	RED 27	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. The concentration in the medicine must be no more than 0.5%.
4265	RED 27 ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. The concentration in the medicine must be no more than 0.5%.
4266	RED ANT	H	Only for use as an active homoeopathic ingredient.
4267	RED CLOVER FLOWER DRY	A, H	
4268	RED CLOVER FLOWER POWDER	A, H	
4269	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4270	RED DEER	A	

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4271	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4272	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4273	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4274	REHMANNIA GLUTINOSA	A, E, H	
4275	REL-1-((1R,2S)-1,2,3,4,5,6,7,8-OCTAHYDRO-1,2,8,8-TETRAMETHYL-2-NAPHTHALENYL)-1-ETHANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4276	RESORCINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4277	RESORCINOL DIMETHYLETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4278	RESVERATROL	A	Only permitted for use in medicines that are for oral routes of administration. The maximum recommended daily dose of the medicine must not contain more than 150 milligrams of resveratrol. The following warning statements are required on the medicine label: - (RESVER) 'Resveratrol may affect the way some medicines work, including Warfarin. Consult your health professional before taking with other medicines (or words to that effect).'; - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)'; and - (CHILD2) 'Not suitable for children'.
4279	RETINOL	A, E	Vitamin A is a mandatory component of retinol. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
4280	RETINOL ACETATE	A, E	Vitamin A is a mandatory component of retinol acetate. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
4281	RETINOL PALMITATE	A, E	Vitamin A is a mandatory component of retinol palmitate. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
4282	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
4283	RHAMNOSE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4284	RHAMNUS CATHARTICA	A, H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4285	RHAMNUS FRANGULA	A, H	Glucofrangulins calculated as glucofrangulin A is a mandatory component of

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

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4286	RHATANY ROOT DRY	A, H	
4287	RHATANY ROOT POWDER	A, H	
4288	RHEUM OFFICINALE	A, E, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum officinale. 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

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

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			- (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'.
4289	RHEUM PALMATUM	A, E, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum palmatum. 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

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			a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4290	RHEUM RHAPONTICUM	A, E, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives

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

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			component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4291	RHEUM TANGUTICUM	A, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum tanguticum. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended';

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

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			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'.
4292	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4293	RHODINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4294	RHODINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
4295	RHODIOLA ROSEA	A	Only for use in oral medicines. Only available for use when the plant preparation is dry root powder, dry root powder as an aqueous extract or dry root powder as a hydroethanolic extract with no more than 70%

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			ethanol v/v.
4296	RHODODENDRON AUREUM	A, H	
4297	RHODODENDRON FERRUGINEUM	A, H	Arbutin is a mandatory component of Rhododendron ferrugineum. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
4298	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4299	RHUBARB	E, H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhubarb. 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

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

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			recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4300	RHUBARB ROOT DRY	A, H	When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of rhubarb root dry. 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

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			label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4301	RHUBARB ROOT POWDER	A, H	When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of rhubarb root powder. When used in oral medicines,

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

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			When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4302	RHUS AROMATICA	A, E, H	
4303	RHUS CHINENSIS	A, H	
4304	RHUS GLABRA	A, E, H	
4305	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4306	RIBES GROSSULARIA	A, E, H	
4307	RIBES NIGRUM	A, E, H	
4308	RIBOFLAVIN	A, E	
4309	RIBOFLAVIN SODIUM PHOSPHATE	A, E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of

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			this medicine contains [state quantity and units] of sodium (or words to that effect).'
4310	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4311	RIBOFLAVINE	A, E	
4312	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4313	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4314	RIBOSE	A	Only for use in oral medicines. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:

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			- (LACT) ‘Contains lactose' (or words to that effect).
4315	RICE	E	
4316	RICE BRAN	E	
4317	RICE BRAN OIL	E	
4318	RICE BRAN WAX	A, E, H	
4319	RICE STARCH	E	
4320	RICE VINEGAR	E	
4321	RICE WINE	E	Ethanol is a mandatory component of Rice wine. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) ‘Contains ethanol’ or ‘contains alcohol’
4322	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4323	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4324	ROBINIA PSEUDOACACIA	A, E, H	When the herbal substance is derived from plant parts other than the leaf or flower, the maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.

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4325	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4326	ROSA ARVENSIS	A, E, H	
4327	ROSA CANINA	A, E, H	
4328	ROSA CYMOSA	A, E, H	
4329	ROSA EGLANTERIA	A, E, H	
4330	ROSA GALLICA	A, E, H	
4331	ROSA LAEVIGATA	A, E, H	
4332	ROSA MULTIFLORA	A, E, H	
4333	ROSA ROXBURGHII FRUIT EXTRACT	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 0.002%.
4334	ROSA RUGOSA	A, E, H	
4335	ROSA VILLOSA	A, E, H	
4336	ROSA X CENTIFOLIA	A, E, H	
4337	ROSA X DAMASCENA	A, E, H	
4338	ROSANA	E	Permitted for use only in combination with 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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4339	ROSE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4340	ROSE FRUIT FRESH	A, E, H	
4341	ROSE HIP	E	
4342	ROSE OIL	A, E, H	
4343	ROSE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4344	ROSEMARY OIL	A, E, H	Safrole is a mandatory component of Rosemary oil. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than

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			1%.
4345	ROSMARINUS OFFICINALIS	A, E, H	Camphor and cineole are mandatory components of Rosmarinus officinalis. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations other than essential oils or distillates, when the concentration of

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			cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
4346	ROYAL JELLY	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly. The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4347	ROYAL JELLY FRESH	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Royal jelly fresh. The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4348	ROYAL JELLY LYOPHILISED	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly lyophilised. The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4349	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4350	RUBIA CORDIFOLIA	A, H	
4351	RUBIA TINCTORUM	A, H	
4352	RUBUS CHINGII	A, H	
4353	RUBUS CORCHORIFOLIUS	A, H	
4354	RUBUS COREANUS	A, E, H	
4355	RUBUS FRUTICOSUS	A, E, H	
4356	RUBUS IDAEUS	A, E, H	
4357	RUBUS OCCIDENTALIS	A, E, H	
4358	RUBUS PARVIFOLIUS	A, H	
4359	RUBUS ROSIFOLIUS	A, H	
4360	RUDBECKIA HIRTA	A, H	
4361	RUE OIL	A, H	
4362	RUM	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4363	RUMEX ACETOSA	A, H	
4364	RUMEX ACETOSELLA	A, H	
4365	RUMEX CONGLOMERATUS	A, H	
4366	RUMEX CRISPUS	A, E, H	
4367	RUMEX PULCHER	A, H	
4368	RUMEX SCUTATUS	A, H	
4369	RUSCUS ACULEATUS	A, H	
4370	RUTA GRAVEOLENS	A, E, H	
4371	RUTOSIDE	A, E	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4372	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4373	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.
4374	S-ISOPROPYL 3-METHYLTHIOCROTONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4375	SABINENE HYDRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4376	SACCHARIDE ISOMERATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.66%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4377	SACCHARIN	E	When the medicine is for oral use, the following warning statement is required on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect).
4378	SACCHARIN SODIUM	E	The medicine requires the following warning statement on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect). 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).'
4379	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4380	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4381	SACCHAROMYCES CERVISIAE POLYSACCHARIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 1%.
4382	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4383	SACCHARUM OFFICINARUM	A, E, H	
4384	SAFFLOWER OIL	A, E, H	
4385	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4386	SAGE LEAF DRY	A, E, H	Thujone is a mandatory component of Sage leaf dry. The concentration of thujone in the medicine must be no more than 4%.
4387	SAGE LEAF POWDER	A, H	Thujone is a mandatory component of Sage leaf powder. The concentration of thujone in the medicine must be no more than 4%.
4388	SAGE OIL DALMATIAN	A	Thujone is a mandatory component of Sage oil dalmatian. The concentration of thujone in the medicine must be no more than 4%. When the concentration of

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Sage oil dalmatian in the medicine is more than 10% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert and child resistant closure must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
4389	SAGE OIL SPANISH	A, E, H	
4390	SALICORNIA EUROPAEA EXTRACT	E	Only for use in topical medicines for dermal use 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 0.002%.
4391	SALICYLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4392	SALICYLIC ACID	E, H	Only for use in topical

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines for dermal application. The concentration in the medicine must be no more than 40%.
4393	SALIX ALBA	A, E, H	
4394	SALIX DAPHNOIDES	A, H	
4395	SALIX DISCOLOR	A, H	
4396	SALIX FRAGILIS	A, H	
4397	SALIX NIGRA	A, H	
4398	SALIX PURPUREA	A, H	
4399	SALSOLA KALI	A, H	
4400	SALVIA CHINENSIS	A, H	
4401	SALVIA FRUTICOSA	A, H	
4402	SALVIA HISPANICA	A, E, H	
4403	SALVIA LAVANDULAEFOLIA	A, H	
4404	SALVIA MILTIORRHIZA	A, H	
4405	SALVIA OFFICINALIS	A, E, H	Thujone is a mandatory component of Salvia officinalis. The concentration of thujone in the medicine must be no more than 4%.
4406	SALVIA SCLAREA	A, E, H	
4407	SAMBUCUS CANADENSIS	A, H	
4408	SAMBUCUS EBULUS	A, H	
4409	SAMBUCUS NIGRA	A, E, H	
4410	SANDALWOOD OIL EAST INDIAN	A, E, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4411	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4412	SANICULA EUROPAEA	A, H	
4413	SANTALUM ALBUM	A, E, H	
4414	SANTALUM SPICATUM	A, E, H	The route of administration must be topical or inhalation. The plant preparation must be oil. The plant part must be root or stem wood including heartwood.
4415	SAPINDUS MUKOROSSI	A, H	
4416	SAPONARIA OFFICINALIS	A, H	
4417	SAPOSHNIKOVIA DIVARICATA	A, H	
4418	SARCOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4419	SARGASSUM FUSIFORME	A, H	Iodine is a mandatory component of Sargassum fusiforme. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
4420	SARGASSUM SILIQUASTRUM	A, H	Iodine is a mandatory component of Sargassum siliquastrum. 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.
4421	SASSAFRAS ALBIDUM	A, H	Safrole is a mandatory component of Sassafras albidum. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
4422	SATUREIA HORTENSIS	A, H	
4423	SATUREIA MONTANA	A, H	
4424	SAUROPUS SPATULIFOLIUS	A, H	
4425	SAURURUS CHINENSIS	A, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4426	SAUSSUREA COSTUS	A, H	
4427	SAVORY OIL SUMMER	A, H	
4428	SAXIFRAGA GRANULATA	A, E, H	
4429	SAXIFRAGA STOLONIFERA	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 not be more than 0.0816%.
4430	SCAPHIUM SCAPHIGERUM	A, H	
4431	SCHEFFLERA HEPTAPHYLLA	A, H	
4432	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4433	SCHINUS MOLLE	A, H	
4434	SCHINUS MOLLE OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4435	SCHISANDRA CHINENSIS	A, E, H	
4436	SCHIZONEPETA TENUIFOLIA	A, E, H	
4437	SCHOENOCAULON OFFICINALE	A, H	The maximum recommended daily dose must contain no more than the equivalent of 1mg of the dry herbal material.
4438	SCLAREOL	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4439	SCLAREOLIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4440	SCLERANTHUS ANNUUS	A, H	
4441	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4442	SCOPOLIA CARNIOLICA	A, H	The concentration of equivalent dry Scopolia carniolica in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4443	SCROPHULARIA NINGPOENSIS	A, H	
4444	SCROPHULARIA NODOSA	A, H	
4445	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4446	SCUTELLARIA BAICALENSIS	A, E, H	
4447	SCUTELLARIA BARBATA	A, H	
4448	SCUTELLARIA LATERIFLORA	A, E, H	
4449	SEA WHIP EXTRACT	E	Only for use in topical

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4450	SEC BUTYL 3-METHYLBUT-2-ENETHIOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4451	SEC-BUTYL THIOISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4452	SECALE CEREALE	A, H	Gluten is a mandatory component of Secale cereale when the plant part is seed and the route of administration is other than topical and mucosal.
4453	SEDUM ACRE	A, H	
4454	SELAGINELLA TAMARISCINA	A, H	
4455	SELENICEREUS GRANDIFLORUS	A, E, H	
4456	SELENIUM	H	Only for use as an active

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			homoeopathic ingredient. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4457	SELENOCYSTEINE	A	Selenium is a mandatory component of Selenocysteine for oral and sublingual use. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.'
4458	SELENOMETHIONINE	A	Selenium is a mandatory component of

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Selenomethionine for oral and sublingual use. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micograms for adults of selenium from dietary supplements should not be exceeded.'
4459	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4460	SEMECARPUS ANACARDIUM	A, H	When the plant part is other than seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
4461	SEMOLINA	E	
4462	SEMPERVIVUM TECTORUM	A, H	
4463	SENEGA ROOT DRY	A, H	
4464	SENEGA ROOT POWDER	A, H	
4465	SENNA ALEXANDRINA	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna alexandrina. When used in oral medicines,

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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4466	SENNA FRUIT ALEXANDRIAN DRY	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian dry. 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

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

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (LAX2) 'Prolonged use may cause serious bowel problems'.
4467	SENNA FRUIT ALEXANDRIAN POWDER	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian powder. 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4468	SENNA FRUIT TINNEVELLY DRY	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly dry. 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

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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
4469	SENNA FRUIT TINNEVELLY POWDER	A, H	When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly powder. 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4470	SENNA LEAF DRY	A, H	When for oral or sublingual use, Hydroxyanthracene

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

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			or the chemical component(s)]'; - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4471	SENNA LEAF POWDER	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Leaf Powder. 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

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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4472	SENNA OCCIDENTALIS	A, H	Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna occidentalis when the route of administration is oral administration. 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

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			label: - (LAX1) 'Drink plenty of water' [or words to that effect]. When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine 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'.
4473	SENNA TORA	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna tora. When used in oral medicines, if the maximum recommended

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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4474	SEPIA	H	Only for use as an active homoeopathic ingredient.
4475	SEQUOIA SEMPERVIRENS	A, H	
4476	SEQUOIADENDRON GIGANTEUM	A, H	
4477	SERENOA REPENS	A, H	
4478	SERINE	A, E	
4479	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4480	SESAME OIL	A, E, H	
4481	SESAME SEED	E	
4482	SESAMUM INDICUM	A, E, H	
4483	SETARIA ITALICA	A, H	
4484	SHARK CALCIUM CHONDROITIN SULFATE	A	

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
4485	SHARK CARTILAGE	A, E	The medicine requires the following warning statement on the medicine label: - (SHARK) 'Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice' (or words to that effect)
4486	SHARK CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
4487	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4488	SHARK SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
4489	SHARK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Shark-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A

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			from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
4490	SHEA BUTTER	E	
4491	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4492	SHELLAC	E	
4493	SHEPHERD'S PURSE HERB DRY	A, H	
4494	SHEPHERD'S PURSE HERB POWDER	A, H	
4495	SHERRY WINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4496	SIGESBECKIA ORIENTALIS	A, E, H	
4497	SILICA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4498	SILICA DIMETHYL SILYLATE	E	Only for use in topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4499	SILICA SILYLATE	E	Only for use in topical medicines for dermal application.
4500	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4501	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4502	SILICONE QUATERNIUM-8	E	Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%. The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect).
4503	SILVER	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
4504	SILVER BEET	E, H	
4505	SILVER BOROSILICATE	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 should be no more than 0.6%. Silver is a mandatory component of Silver borosilicate when the route of administration is topical. The concentration of silver in the medicine must be no more than 1%.
4506	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4507	SILYBUM MARIANUM	A, E, H	
4508	SIMABA CEDRON	A, H	
4509	SIMETHICONE	E	
4510	SIMMONDSIA CHINENSIS	A, E, H	
4511	SINAPIS ALBA	A, H	Allyl isothiocyanate is a mandatory component of Sinapis alba when the plant part is seed. 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%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4512	SINAPIS ARVENSIS	A, H	
4513	SINOMENIUM ACUTUM	A, H	
4514	SIPHONESTEGIA CHINENSIS	A, H	
4515	SIRAITIA GROSVENORII	A, E, H	
4516	SISYMBRIUM OFFICINALE	A, H	
4517	SKATOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4518	SKIPJACK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of Shark-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
4519	SLIPPERY ELM BARK DRY	A, H	
4520	SLIPPERY ELM BARK POWDER	A, E, H	
4521	SMILAX ARISTOLOCHIIFOLIA	A, H	
4522	SMILAX CHINA	A, H	
4523	SMILAX GLABRA	A, H	
4524	SMILAX OFFICINALIS	A, E, H	
4525	SMILAX ORNATA	A, E, H	
4526	SMOKE EXTRACT	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4527	SODIUM ACETATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4528	SODIUM ACETYLATED HYALURONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4529	SODIUM ACID CITRATE	A, E, H	When used as an active ingredient, only for use in oral medicines. When used as an active, only for use in oral medicines. When for oral or sublingual use and the total amount of sodium from all ingredients in the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
4530	SODIUM ACRYLATES 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 0.8%.
4531	SODIUM ACRYLATES CROSSPOLYMER-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.7 % (w/w).
4532	SODIUM ACRYLOYDIMETHYLTAURATE/ VP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% (w/w).

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4533	SODIUM ALGINATE	E	
4534	SODIUM ASCORBATE	A, E, H	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).'
4535	SODIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When used in a sunscreen, the concentration in the medicine must be no more than 0.1%. When used in products other than sunscreens, the concentration in the medicine must be no more than 0.5%.
4536	SODIUM ASCORBYL/CHOLESTERYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4537	SODIUM BENZOATE	E	Medicines containing benzoates require the following warning statement on the medicine label: - (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source. 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).'
4538	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	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).

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4539	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4540	SODIUM BICARBONATE	A, E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms. Medicines for use as oral rehydration therapy are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.' c) the medicine requires the following warning statements on the medicine label: - (UOAD) 'Use only as directed.' - (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice (or words to that effect).' - (DIAR3) 'If diarrhoea persists, seek medical advice.'
4541	SODIUM BISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4542	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4543	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4544	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4545	SODIUM CARBONATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4546	SODIUM CARBONATE MONOHYDRATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
4547	SODIUM CARBOXYMETHYL BETAGLUCAN	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 0.005%.
4548	SODIUM CARRAGEENAN	E	
4549	SODIUM CASEINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4550	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4551	SODIUM CHLORIDE	A, E, H	
4552	SODIUM CHONDROITIN	A, E	When used as an excipient

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	SULFATE		ingredient: a) only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye; b) the concentration in the medicine must not be more than 0.001%. When used as an active ingredient: a) the route of administration must only be oral; b) the maximum daily dose must not provide more than 1,200 mg of sodium chondroitin sulfate; c) the following statements must be included on the medicine label: - (ADULT) 'Adults only' (or words to that effect); - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
4553	SODIUM CITRATE	A, E	Only for oral use when used as an active ingredient. 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

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			this medicine contains [state quantity and units] of sodium' (or words to that effect).
4554	SODIUM CITRATE DIHYDRATE	A, E	Only for oral use when used as an active ingredient. 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).
4555	SODIUM COCO PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
4556	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4557	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4558	SODIUM CYCLAMATE	E	When for oral or sublingual use

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
4559	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4560	SODIUM DNA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4561	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4562	SODIUM ERYTHORBATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
4563	SODIUM ETHYL HYDROXYBENZOATE	E	
4564	SODIUM FLUORIDE	A, E, H	Fluoride is a mandatory component of Sodium fluoride. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When used as an active ingredient, it is subject to the following conditions: a) Only for use in combination with at least one other listable therapeutically active ingredient. b) The concentration of fluoride ion must be no more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.' When for oral or sublingual use and the total amount of sodium from all ingredients in the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
4565	SODIUM FUMARATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4566	SODIUM GLYCEROPHOSPHATE	A, E, H	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).'

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4567	SODIUM HYALURONATE	E	Only for use in topical medicines for dermal application.
4568	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4569	SODIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%. 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 used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4570	SODIUM HYDROXYCITRATE	A	
4571	SODIUM HYDROXYETHYL ACRYLATE/ACRYLOYLDIMETHYL TAURATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 1.5%.
4572	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4573	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of Sodium hypochlorite. The concentration of chlorine in the medicine must be no more than 4%. 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).
4574	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4575	SODIUM LACTATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
4576	SODIUM LAURETH SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4577	SODIUM LAUROAMPHOACETATE	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%.
4578	SODIUM LAUROYL METHYL ISETHIONATE	E	Only for use in wash-off 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

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 11%.
4579	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4580	SODIUM LAURYL PHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4581	SODIUM LAURYL SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4582	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
4583	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4584	SODIUM MANNOSE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4585	SODIUM METABISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4586	SODIUM METAPHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must not be more than 0.1%.
4587	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine must be no more than 2%.
4588	SODIUM METHYL HYDROXYBENZOATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4589	SODIUM MOLYBDATE DIHYDRATE	A	Only for use in oral medicines. Molybdenum is a mandatory component of Sodium molybdate dihydrate. The percentage of molybdenum from sodium molybdate dihydrate should be calculated based on the molecular weight of sodium molybdate dihydrate. The maximum daily dose of molybdenum from Sodium molybdate dihydrate must be no more than 125 micrograms.
4590	SODIUM MONOFLUOROPHOSPHATE	A	Fluoride is a mandatory component of sodium monofluorophosphate. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When used as an active ingredient, it is subject to the following conditions: a) Only for use in combination with at least one other listable therapeutically active ingredient. b) The concentration of fluoride ion must be no more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			mg/kg, the medicine requires the following statements on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.' 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).'
4591	SODIUM MYRISTOYL GLUTAMATE	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 0.0164%.
4592	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4593	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
4594	SODIUM PANTOTHENATE	A, E, H	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).
4595	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4596	SODIUM PERBORATE	A, H	Boron is a mandatory component of sodium perborate. When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron. When used in preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron from all ingredients in the product must not exceed 3500 mg/kg or 3500 mg/L or 0.35%. 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 label:

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label: - (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). (b) When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label: - (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or

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			- (ADULT) 'Adults only' (or words to that effect). (c) When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label: - (BORON) 'Contains boron' (or words to that effect). (d) When the medicine is for topical use for dermal application, the following warning statement is required on the label: - (BROKEN) 'Use on unbroken skin only' (or words to that effect).
4597	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.
4598	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4599	SODIUM POLYACRYLATE STARCH	E	Only to be used in a medicine where Procter & Gamble Australia Pty Ltd (Client ID 11364), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 27 September 2020. 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 not be more than 1%.
4600	SODIUM POLYMETAPHOSPHATE	E	
4601	SODIUM PROPIONATE	E	Only for use in topical medicines for dermal application.
4602	SODIUM PROPYL HYDROXYBENZOATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4603	SODIUM RNA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
4604	SODIUM SELENATE	A, H	Selenium is a mandatory component of sodium selenate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4605	SODIUM SELENATE DECAHYDRATE	A	Selenium is a mandatory component of sodium selenate

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			decahydrate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4606	SODIUM SELENITE	A, H	Selenium is a mandatory component of Sodium selenite. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.’
4607	SODIUM SELENITE PENTAHYDRATE	A	Selenium is a mandatory component of Sodium selenite pentahydrate. Oral medicines must contain

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4608	SODIUM SILICATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. 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).
4609	SODIUM STARCH GLYCOLLATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the

Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
4610	SODIUM STARCH GLYCOLLATE TYPE A	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4611	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4612	SODIUM STEAROXY PG-HYDROXYETHYLCELLULOSE SULFONATE	E	Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
4613	SODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4614	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4615	SODIUM STEARYL PHTHALAMATE	E	Only for use in medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4616	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4617	SODIUM SULFATE	A, E, H	When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label: - (LAX4) 'Substance may have a laxative effect'. 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4618	SODIUM SULFATE DECAHYDRATE	A, E, H	When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label: - (LAX4) 'Substance may have a laxative effect'. 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).
4619	SODIUM SULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect). Medicines containing sulfites

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4620	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application. Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4621	SODIUM TRIPOLYPHOSPHATE	E	Only for use when the route of administration is topical for dermal application, mucous membrane (buccal mucosa) or dental. Not to be included in topical medicines intended for use in the eye. The concentration in the 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**
4622	SOLANUM DULCAMARA	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum dulcamara. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4623	SOLANUM FEROX	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum ferox. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4624	SOLANUM LYCOCARPUM FRUIT EXTRACT	E	Only for use in topical medicines for dermal use and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4625	SOLANUM MELONGENA	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum melongena. When for internal use, the maximum recommended daily dose must not provide more

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 10mg of steroidal alkaloids calculated as solanine.
4626	SOLANUM NIGRUM	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum nigrum. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4627	SOLANUM TUBEROSUM	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum tuberosum. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4628	SOLIDAGO GIGANTEA	A, H	
4629	SOLIDAGO GIGANTEA MIS	A, E, H	
4630	SOLIDAGO VIRGAUREA	A, E, H	
4631	SOLUBLE MAIZE STARCH	E	
4632	SOLUBLE POTATO STARCH	E	
4633	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4634	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4635	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4636	SOLVENT YELLOW 172	E	Permitted for use only as a colour for topical use. The concentration in the medicine must be no more than 0.3%.
4637	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4638	SOPHORA FLAVESCENS	A, E, H	
4639	SOPHORA TONKINENSIS	A, H	
4640	SORBIC ACID	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4641	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4642	SORBITAN MONO-OLEATE	E	
4643	SORBITAN MONOLAURATE	E	
4644	SORBITAN MONOSTEARATE	E	
4645	SORBITAN OLEATE	E	

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4646	SORBITAN OLIVATE	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 10%.
4647	SORBITAN PALMITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
4648	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4649	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4650	SORBITAN STEARATE	E	
4651	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4652	SORBITOL	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
4653	SORBITOL SOLUTION (70 PER CENT) (CRYSTALLISING)	A, E	Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (crystallising). 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. When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).'
4654	SORBITOL SOLUTION (70 PER CENT) (NON-CRYSTALLISING)	A, E	Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (non-crystallising). When used as an active

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			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. When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).'
4655	SORBUS AUCUPARIA	A, H	
4656	SORBUS DOMESTICA	A, H	
4657	SORGHUM	E	
4658	SORGHUM VULGARE	A, H	
4659	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.

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4660	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4661	SOY POLYSACCHARIDE	E	
4662	SOY PROTEIN	E	
4663	SOY STEROL	E	
4664	SOYA BEAN	E	
4665	SOYA BRAN	E	
4666	SOYA OIL	A, E, H	
4667	SOYBEAN FLOUR	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4668	SOYBEAN GLYCERIDES	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 4%.
4669	SPARGANIUM STOLONIFERUM	A, H	
4670	SPARTIUM JUNCEUM	A, H	

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4671	SPATHOLOBUS SUBERECTUS	A, H	
4672	SPEARMINT OIL	A, E, H	Menthol is a mandatory component of spearmint oil. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high

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			concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4673	SPEARMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. Menthol is a mandatory component of spearmint oil terpeneless. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect).

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4674	SPHINGOLIPIDS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4675	SPIGELIA ANTHELMIA	A, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4676	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4677	SPIKE LAVENDER OIL	A, E, H	Camphor is a mandatory component of spike lavender oil. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
4678	SPINACH	E	
4679	SPINACIA OLERACEA	A, E, H	
4680	SPIRODELA POLYRRHIZA	A, H	
4681	SPIRULINA	E	
4682	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
4683	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4684	SPRUCE 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%.
4685	SQUALANE	E	Only for use in topical medicines for dermal application.
4686	SQUALENE	A, E	
4687	SQUID OIL	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'. Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in combination with other ingredients in the medicine and be presented in a therapeutic

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			dosage form for therapeutic use.
4688	SQUILL DRY	A, H	
4689	SQUILL INDIAN DRY	A, H	
4690	SQUILL INDIAN POWDER	A, H	
4691	SQUILL POWDER	A, H	
4692	ST JOHN'S WORT DRY EXTRACT QUANTIFIED	A	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4693	ST JOHN'S WORT HERB DRY	A, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4694	ST JOHN'S WORT HERB POWDER	A, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4695	STACHYS OFFICINALIS	A, E, H	
4696	STACHYS PALUSTRIS	A, H	
4697	STACHYURUS HIMALAICUS	A, H	
4698	STANNIC OXIDE	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 0.005%.
4699	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4700	STAR ANISE OIL	A, E	When the concentration in the medicine is more than 50% and the nominal capacity of the container is equal to or less than 50mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or words to that effect).
4701	STARCH	E	Permitted for use only in combination with other permitted ingredients 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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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4702	STARCH SODIUM OCTENYL SUCCINATE	E	
4703	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4704	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4705	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4706	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4707	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4708	STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 2%. When the medicine is intended to be used on the eye, the medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4709	STEARETH-10	E	Only for use in topical medicines for dermal application.
4710	STEARETH-100	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4711	STEARETH-2	E	Only for use in topical medicines for dermal application.
4712	STEARETH-20	E	Only for use in topical medicines for dermal application.
4713	STEARETH-21	E	Only for use in topical medicines for dermal application.
4714	STEARETH-5	E	Only for use in topical medicines for dermal application.
4715	STEARIC ACID	E	
4716	STEAROPTENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more than 1%.
4717	STEAROXY DIMETHICONE	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 4%.
4718	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4719	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4720	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4721	STEARYL ALCOHOL	E	
4722	STEARYL DIMETHICONE	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 4.5%. The medicine requires the following warning statements

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect) - (EYE) 'Avoid contact with eyes' (or words to that effect).
4723	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4724	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4725	STEARYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4726	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4727	STELLARIA CHAMAEJASME	A, H	
4728	STELLARIA DICHOTOMA	A, H	
4729	STELLARIA MEDIA	A, E, H	
4730	STEMONA JAPONICA	A, H	
4731	STEMONA SESSILIFOLIA	A, H	
4732	STENOTAPHRUM SECUNDATUM	A, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4733	STEPHANIA TETRANDA	A, H	
4734	STERCULIA	A, H	
4735	STERCULIA TRAGACANTHA	A, H	
4736	STERCULIA URENS	A, H	
4737	STEVIA REBAUDIANA	A, E, H	
4738	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4739	STILLINGIA SYLVATICA	A, H	
4740	STORAX PREPARED	A, E, H	
4741	STRAWBERRY	E	
4742	STRAWBERRY ESSENCE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4743	STREPTOCOCCUS SALIVARIUS	A	Only permitted for use in medicines: - that are for oral routes of administration; and - when the strain of Streptococcus salivarius is confirmed to be K12 or M18. The name of the Streptococcus salivarius strain must be declared on the label. The following warning statement is required on the medicine label: - (CHILD5) 'Use in children under 3 years is not recommended'.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4744	STREPTOCOCCUS THERMOPHILUS	A	
4745	STROBILANTHES CUSIA	A, H	
4746	STRONG AMMONIA SOLUTION	E	Ammonia is a mandatory component of dilute ammonia solution. The concentration of ammonia in the medicine must be no more than 0.5%. When for internal use, the concentration in the medicine must be no more than 0.25%.
4747	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4748	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4749	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4750	STRYCHNOS IGNATII	H	Only for use as an active homoeopathic ingredient. Strychnine (of Strychnos spp.) is a mandatory component of Strychnos ignatii. The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4751	STRYCHNOS NUX-VOMICA	A, H	Strychnine (of Strychnos spp.) is a mandatory component of

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Strychnos nux-vomica. The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4752	STYPHNOLOBIUM JAPONICUM	A, E, H	
4753	STYRALLYL PROPIONATE	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%.
4754	STYRAX BENZOIN	A, E, H	
4755	STYRAX 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%.
4756	STYRAX PARALLELONEURUM	A, H	
4757	STYRAX TONKINENSIS	A, H	
4758	STYRENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4759	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4760	STYROLYL 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%.
4761	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4762	SUCCINIC ACID	E	
4763	SUCRALOSE	E	
4764	SUCROSE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4765	SUCROSE ACETATE ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4766	SUCROSE ACETATE PALMITATE STEARATE	E	Only for use in topical medicines for dermal application and not intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
4767	SUCROSE COCOATE	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%.
4768	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
4769	SUCROSE LAURATE	E	When for oral or sublingual use, Sucrose is a mandatory component of Sucrose laurate. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4770	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4771	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4772	SUCROSE POLYCOTTONSEEDATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with the eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4773	SUCROSE STEARATE	E	For use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When for topical use, the concentration in the medicine must be no more than 0.25%. For oral use as a manufacturing aid only. When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit.
4774	SUCROSE TRISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
4775	SUDAN III	E	Permitted for use only as a colour for topical use.
4776	SUGAR CANE WAX ALCOHOLS	A, H	The maximum recommended daily dose must not provide more than 12mg. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).

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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4777	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of Sugarcane. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4778	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4779	SULFATED LOW MOLECULAR WEIGHT FUCANS	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 0.025%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4780	SULFUR DIOXIDE	E	Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4781	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4782	SULFURIC ACID	E, H	Only for use as an active homoeopathic ingredient or excipient ingredient. The concentration in the medicine must be no more than 0.5%.
4783	SULFURISED 1-METHYL-4-(1-METHYLETHENYL)-CYCLOHEXENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4784	SULISOBENZONE	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.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, 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).
4785	SULISOBENZONE SODIUM	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, 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).
4786	SUNFLOWER OIL	A, E, H	
4787	SUNFLOWER SEED	E, H	
4788	SUNSET YELLOW FCF	E	Permitted for use only as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			colour for either topical use or with an oral route of administration.
4789	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
4790	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4791	SWEDE	E	
4792	SWEET ORANGE OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4793	SWEET POTATO	E	
4794	SWERTIA CHIRATA	A, H	
4795	SWIETENIA MAHOGANI	A, H	
4796	SYAGRUS ROMANZOFFIANA	A, E, H	
4797	SYMPHYTUM OFFICINALE	H	When used orally as an active homoeopathic ingredient, the concentration must be a dilution of 12X or more. When used in topical medicines for dermal

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application, the concentration in the preparation must be no more than 10mg/kg or 10mg/L or 0.001%.
4798	SYMPLOCARPUS FOETIDUS	A, H	
4799	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4800	SYNTHETIC TERPENE RESIN	E	Only for use in topical, oral or oral application medicines. When the route of administration is oral, the dosage form must be chewing gum.
4801	SYNTHETIC WAX	E	
4802	SYRINGA RETICULATA	A, H	
4803	SYRINGA VULGARIS	A, H	
4804	SYZYGIUM AROMATICUM	A, E, H	When the plant preparation is oil or distillate and the concentration of this oil or distillate in the product is greater than 25%, the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the plant preparation is oil or distillate, the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			concentration of this oil or distillate in the medicine is greater than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, a child resistant closure and restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate, the concentration of oil or distillate in the product is greater than 25% and the nominal capacity of the container is less than 15 millilitres, a restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate and the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of the oil or distillate and the concentration of oil or distillate in the product must not be greater than 25%.
4805	SYZYGIUM CUMINI	A, H	
4806	SYZYGIUM JAMBOS	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 not be more than 0.0693%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4807	TABEBUIA SERRATIFOLIA	A, E, H	
4808	TAGETES ERECTA	A, H	
4809	TAGETES MINUTA	A, E, H	
4810	TAGETES 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%.
4811	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4812	TALLOW	E	Only for use in topical medicines for dermal application.
4813	TALLOW GLYCERIDES	E	
4814	TAMARINDUS INDICA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4815	TAMARIX APHYLLA	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4816	TAMARIX CHINENSIS	A, H	
4817	TAMARIX GALLICA	A, H	
4818	TAMUS COMMUNIS	A, H	If the plant part is fruit or root, the maximum recommended daily dose must be no more than 1mg of the equivalent dry fruit or dry root of Tamus communis.
4819	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4820	TANACETUM PARTHENIUM	A, E, H	
4821	TANACETUM VULGARE	A, H	Oil (of Tanacetum vulgare) is a mandatory component of Tanacetum vulgare. The concentration of oil (of Tanacetum vulgare) in the medicine must be no more than 0.8%.
4822	TANGERINE 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%.
4823	TANGERINE OIL COLDPRESSED	A, E, H	When used internally, oxedrine is a mandatory component of

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			tangerine oil coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
4824	TANNIC ACID	E	
4825	TAPIOCA STARCH	E	
4826	TARAXACUM MONGOLICUM	A, E, H	
4827	TARAXACUM OFFICINALE	A, E, H	
4828	TARO	E	
4829	TARRAGON OIL	A, E, H	
4830	TARTARIC ACID	E	
4831	TARTRAZINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4832	TARTRAZINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4833	TASMANNIA LANCEOLATA	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4834	TAURINE	A, E	
4835	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4836	TERMINALIA ARJUNA	A	Only for use in oral medicines. Only for use when the plant part is bark. The maximum recommended daily dose must be no more than 6 grams of Terminalia arjuna dried bark or its extract equivalents. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (CHILD2) 'Not suitable for children'.
4837	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4838	TERMINALIA CATAPPA	A, H	
4839	TERMINALIA CHEBULA	A, H	
4840	TERMINALIA FERDINANDIANA	A, E, H	Only for use when the plant

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			part is fruit flesh, fruit flesh dry or the preparation is as an aqueous extract of the fruit flesh. When used as an excipient, the ingredient is 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. When used as an excipient, the concentration in the medicine must be no more than 0.3%.
4841	TERMINALIA SERICEA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. Only for use when the plant part is root bark. Only methanol/water (90:10; V/V) extract of Terminalia sericea bark of the root is approved. The concentration in the medicine must be no more than 0.1%.
4842	TERPINEN-4-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

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%.
4843	TERPINEOL	E	
4844	TERPINEOL 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%.
4845	TERPINOLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4846	TERPINYL 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
4847	TERPINYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
4848	TERPINYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4849	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4850	TERT-BUTYL HYDROQUINONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4851	TERT-BUTYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%.
4852	TERT-BUTYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4853	TETRACLINIS ARTICULATA	A, E, H	
4854	TETRADECYL AMINOBUTYROYLVALYLAMINOBUTYRIC UREA TRIFLUOROACETATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
4855	TETRADIUM RUTICARPUM	A, H	When for internal use, oxedrine is a mandatory component of Tetradium ruticarpum. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4856	TETRAHEXYLDECYL ASCORBATE	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1%.
4857	TETRAHYDRO LINALYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4858	TETRAHYDRO PARA-METHYLQUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4859	TETRAHYDRO-6-(3-PENTENYL)-2H-PYRAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4860	TETRAHYDRODIFERULOYLMETHANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4861	TETRAHYDROFURFURYL 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%.
4862	TETRAHYDROGERANYL 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%.
4863	TETRAHYDROLINALOOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4864	TETRAHYDROMUGUOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
4865	TETRAHYDROMYRCENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4866	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4867	TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4868	TETRAPANAX PAPYRIFER	A, H	
4869	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4870	TETRASODIUM PYROPHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
4871	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4872	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4873	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4874	THAPSIA GARGANICA	A, H	
4875	THAUMATIN	E	
4876	THEASPIRANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4877	THEMEDA TRIANDRA	A, H	
4878	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma cacao. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ e) When the maximum

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
4879	THEOBROMA OIL	A, E, H	
4880	THIAMINE	A, E	
4881	THIAMINE HYDROCHLORIDE	A, E	
4882	THIAMINE NITRATE	A, E	
4883	THIOCINEOLE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4884	THIOTAURINE	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			0.02%.
4885	THLASPI ARVENSE	A, E, H	
4886	THREONINE	A, E	
4887	THUJA OCCIDENTALIS	A, H	
4888	THUJA PLICATA	A, E, H	
4889	THYME HERB DRY	A, E, H	
4890	THYME OIL	A, E, H	When the concentration of Thyme oil in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the warning statement: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4891	THYMOL	A, E	When used as an active ingredient, the medicine must be medicated space spray or medicated throat lozenges. When used as an excipient, only for use in medicated throat lozenges or topical medicines for dermal applications.
4892	THYMUS CAPITATUS	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4893	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4894	THYMUS MASTICHINA	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4895	THYMUS SERPYLLUM	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4896	THYMUS VULGARIS	A, E, H	When the plant preparation is oil or distillate, the nominal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			capacity of the container must be no more than 25 millilitres. When the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4897	THYMUS VULGARIS MIS	A, E, H	When the plant preparation is an oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus vulgaris mis oil or distillate in the preparation is greated than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4898	THYMUS ZYGIS	A, H	When the plant preparation is an oil or a distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus zygis oil or distillate in the preparation is greater

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4899	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4900	TILACTASE	A	Must be derived from Aspergillus oryzae and comply with the relevant USP monograph. When the dosage form is undivided, the units 'acid lactase units per gram' and 'Thousand acid lactase units per gram' are permitted. When the dosage form is divided, the units 'acid lactase units' and 'thousand acid lactase units' are permitted.
4901	TILIA CORDATA	A, E, H	
4902	TILIA PLATYPHYLLOS	A, E, H	
4903	TILIA TOMENTOSA	A, H	
4904	TILIA X VULGARIS	A, E, H	
4905	TILIANTOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1%.
4906	TIN	H	Only for use as an active homoeopathic ingredient.
4907	TINOSPORA CORDIFOLIA	A, H	
4908	TINOSPORA SINENSIS	A, H	
4909	TITANIUM DIOXIDE	A, E	For use as an active ingredient only in sunscreens for dermal application. The concentration in sunscreens must be no more than 25%. For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. Not to be included in medicines intended for use in the eye. When used in primary sunscreen products, 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).
4910	TOCOCYSTEAMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 0.01%.
4911	TOCOFERSOLAN	E	Only for oral and topical use. When for oral use, the concentration in the medicine must be no more than 10% w/w. When used in topical medicines for dermal application, it is not to be included in medicines intended for use in the eye. When for topical use, the concentration in the medicine must be no more than 0.1%
4912	TOCOPHEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4913	TOCOPHERYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. The concentration in the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 0.05%
4914	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4915	TOCOPHERYL NICOTINATE	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 not exceed 0.3%.
4916	TOLU BALSAM	A, E, H	
4917	TOLUENE	E	The residual solvent limit for toluene is 8.9 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.089%.
4918	TOLYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4919	TOLYLALDEHYDE	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	GLYCERYLACETAL		combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4920	TOMATO	E	
4921	TONKA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4922	TONKA BEAN EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4923	TONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4924	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4925	TOXICODENDRON PUBESCENS	H	Only for use as an active homoeopathic ingredient. The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron pubescens.
4926	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4927	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4928	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4929	TRACHYSPERMUM AMMI	A, E	Only for use in oral medicines when the plant part is fruit or seed. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect).

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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4930	TRAGACANTH	A, E	
4931	TRAMETES VERSICOLOR	A, H	
4932	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4933	TRANS,TRANS-2,4-DECADIEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4934	TRANS,TRANS-2,4-HEXADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 13.5 mg of Trans,Trans-2,4-Hexadienal.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4935	TRANS-1-(2,4,4-TRIMETHYL-2-CYCLOHEXEN-1-YL)-2-BUTEN-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%.
4936	TRANS-2-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4937	TRANS-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%.
4938	TRANS-2-HEPTEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
4939	TRANS-2-HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4940	TRANS-2-HEXENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4941	TRANS-2-HEXENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4942	TRANS-2-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4943	TRANS-2-HEXENYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4944	TRANS-2-HYDROXYCINNAMIC 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%.
4945	TRANS-2-UNDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4946	TRANS-3-HEXENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

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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%.
4947	TRANS-4-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4948	TRANS-8-(1-METHYLETHYL)-1-OXASPIRO(4.5)DECAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4949	TRANS-ETHYL 2-OCTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4950	TRANS-METHYL-2-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
4951	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of Treacle. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4952	TREEMOSS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. When included in a medicine for use on the lips the concentration of treemoss absolute must be no more than

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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			0.02%. When for dermal use or use on the hair the concentration of treemoss absolute must be no more than 0.1% The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
4953	TREFRIW WELLS MINERAL WATER	A	When for internal use, iron is a mandatory component of Trefriw Wells mineral water. Solid dosage forms containing more than 5 milligrams of elemental iron in each dosage unit are required to have a child resistant closure. Liquid Preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. Only able to be used when presented in single use sachets for therapeutic use as an iron supplement.
4954	TREHALOSE DIHYDRATE	E	When for oral use and the quantity of trehalose dihydrate per maximum recommended daily dose exceeds 20 grams, the quantity of trehalose dihydrate must be declared on the label.
4955	TREMELLA FUCIFORMIS	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4956	TRIACETIN	E	
4957	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4958	TRIADICA SEBIFERA	A, H	
4959	TRIBASIC POTASSIUM PHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of tribasic potassium phosphate. When used in a solid medicine containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid medicine containing this ingredient, the pH of the medicine must be no more than 11.5.
4960	TRIBASIC SODIUM PHOSPHATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4961	TRIBEHENIN	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 6%.
4962	TRIBEHENIN PEG-20 ESTERS	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 6%.
4963	TRIBULUS TERRESTRIS	A, E, H	
4964	TRIBUTYL ACETYLCITRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4965	TRICALCIUM PHOSPHATE	E	
4966	TRICAPRYLIN	E	Only for use in topical

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4967	TRICAPRYLYL CITRATE	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 7%.
4968	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4969	TRICHLOROMETHYLPHENYLCARBINYL 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%.
4970	TRICHODERMA VIRIDE	A, E, H	
4971	TRICHOSANTHES KIRILOWII	A, E, H	
4972	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.

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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
4973	TRICYCLODECENYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4974	TRIDECANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4975	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4976	TRIDECETH-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.
4977	TRIDECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			a medicine must be no more than 1%.
4978	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
4979	TRIDECYL NEOPENTANOATE	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 23%.
4980	TRIDECYL SALICYLATE	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%.
4981	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
4982	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
4983	TRIETHOXYCAPRYLYLSILANE	E	Only for use in topical

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines for dermal application 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 1%.
4984	TRIETHYL CITRATE	E	
4985	TRIETHYLENE GLYCOL	E	
4986	TRIFOLIUM PRATENSE	A, E, H	
4987	TRIFOLIUM REPENS	A, H	
4988	TRIGONELLA FOENUM-GRAECUM	A, E, H	
4989	TRIHYDROXYPALMITAMIDOHYDROXYPROPYL MYRISTYL ETHER	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 0.02%.
4990	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
4991	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
4992	TRIISODECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 5%.
4993	TRIISONONANOIN	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%.
4994	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
4995	TRILAURIN	E	Only for use in topical medicines for dermal application.
4996	TRILISA ODORATISSIMA	A, H	
4997	TRILLIUM ERECTUM	A, H	
4998	TRIMETHOXYCAPRYLYL SILANE	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 0.25%.
4999	TRIMETHYL HYDROXYPENTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance concentration in a medicine must be no more than 1%.
5000	TRIMETHYL UNDECYLENIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5001	TRIMETHYL-BICYCLO-HEPTANE-SPIROCYCLOHEXENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5002	TRIMETHYLBENZENEPROPANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5003	TRIMETHYLHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
5004	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5005	TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5006	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5007	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient.
5008	TRIOCTANOIN	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%.
5009	TRIOCTYLDODECYL CITRATE	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 12%.
5010	TRIOLEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
5011	TRIOSTEUM PERFOLIATUM	A, H	
5012	TRIOXAUNDECANEDIOIC ACID	E	
5013	TRIPAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5014	TRIPEPTIDE-1	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
5015	TRIS-BIPHENYL TRIAZINE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			intended for use in the eye. The concentration in the medicine must not be more than 10%. When used topically, the dosage form must not be spray. When used in primary sunscreen products, 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).
5016	TRISILOXANE	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 40%.
5017	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
5018	TRISODIUM ETHYLENEDIAMINE DISUCCINATE	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			0.2%.
5019	TRISODIUM NTA	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 0.005%.
5020	TRISTEARIN	E	
5021	TRITICUM AESTIVUM	A, E, H	Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal.
5022	TRITICUM DURUM	A, E, H	Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal.
5023	TRIUNDECANOIN	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 11.2%.
5024	TROLAMINE	E	Only for use in topical medicines for dermal application.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration in the medicine must be no more than 5%.
5025	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
5026	TROLAMINE SALICYLATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 12%. When used in primary sunscreen products, 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).
5027	TROLLIUS CHINENSIS	A, H	
5028	TROMETAMOL	E	
5029	TROMETAMOL HYDROCHLORIDE	E	
5030	TROPAEOLUM MAJUS	A, E, H	
5031	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5032	TROPOLONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
5033	TSUGA CANADENSIS	A, H	
5034	TULIPA EDULIS	A, H	Colchicine is a mandatory component of Tulipa edulis. The concentration of colchicine in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
5035	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5036	TURNERA DIFFUSA	A, E, H	Arbutin is a mandatory component of Turnera diffusa. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
5037	TURNIP	E	
5038	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			25%.
5039	TYPHA ANGUSTIFOLIA	A, H	
5040	TYPHA LATIFOLIA	A, H	
5041	TYPHONIUM GIGANTEUM	A, H	
5042	TYROSINE	A, E	