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

Note: See sections 5, 6 and 6A.

Permissible ingredients and requirements

Column 1	Column 2	Column 3	Column 4
Item	**Ingredient Name**	**Purpose**	**Specific requirements**
3640	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%.
3641	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%.
3642	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 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).
3643	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%.
3644	PAEONIA LACTIFLORA	A, E, H	
3645	PAEONIA OBOVATA	A, H	
3646	PAEONIA SUFFRUTICOSA	A, E, H	
3647	PAEONIA VEITCHII	A, H	
3648	PALIURUS SPINA-CHRISTI	A, H	
3649	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3650	PALM FRUIT OIL	A, E, H	
3651	PALM GLYCERIDES	E	
3652	PALM KERNEL OIL	A, E, H	
3653	PALM TOCOTRIENOLS COMPLEX	A, H	
3654	PALMARIA PALMATA	A, H	
3655	PALMAROSA OIL	A, E, H	
3656	PALMIDROL	A	Only permitted for use in medicines limited to oral routes of administration. The maximum recommended daily dose of the medicine must not provide more than 600 mg of palmidrol. The following warning statements (or words to the same effect) are required on the medicine label: - (ANALG) 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.'

			- (ADULT) ‘Adults only.’ - (21DAYS) ‘Not to be used for more than 21 consecutive days.’
3657	PALMITIC ACID	E	
3658	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3659	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%.
3660	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%
3661	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%.
3662	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%.
3663	PALMITOYL TETRAPEPTIDE-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 0.001%.

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3664	PANAX GINSENG	A, E, H	
3665	PANAX JAPONICUS	A, H	
3666	PANAX NOTOGINSENG	A, H	
3667	PANAX PSEUDOGINSENG	A, H	
3668	PANAX QUINQUEFOLIUS	A, H	
3669	PANICUM MILIACEUM	A, H	
3670	PANTETHINE	E	Only for use in topical medicines for dermal application.
3671	PANTHENOL	A, E	
3672	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3673	PANTOLACTONE	E	
3674	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3675	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 0.1%.
3676	PAPAIN	A, E	
3677	PAPER	E	Only for use in topical medicines for dermal application.
3678	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%.
3679	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%.
3680	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 medicine must be no more 1%.
3681	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%.
3682	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%.
3683	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%.
3684	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 medicine must be no more than 5%.
3685	PARA-ETHYL CRESOXYACETATE	E	Para-ethyl cresoxyacetate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing para-ethyl cresoxyacetate must not be more than 1% of the total medicine.
3686	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%.
3687	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%.
3688	PARA-HYDROXYBENZOIC ACID	E	
3689	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%.
3690	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%.
3691	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%.
3692	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3693	PARA-PROPYL ANISOLE	E	Para-propyl anisole must only be included in medicines when in combination with other permitted ingredients as a fragrance and/or flavour proprietary excipient formulation. The total concentration of fragrance proprietary excipient formulations containing para-propyl anisole must not be more than 1% of the total medicine. The total concentration of flavour proprietary excipient formulations containing para-propyl anisole must not be more than 5% of the total medicine.
3694	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%.
3695	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%.
3696	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%.
3697	PARA-TOLYL ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3698	PARAMERIA LAEVIGATA	A, H	
3699	PARIETARIA JUDAICA	A, H	
3700	PARIS POLYPHYLLA	A, H	
3701	PARIS QUADRIFOLIA	A, H	
3702	PARSLEY HERB DRY	A, E, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. The following warning statement is required on the medicine label: - (PREGNT2) ‘Do not use if pregnant or likely to become pregnant.’ unless when: (a) parsley herb dry is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) parsley herb dry is used as an excipient in a flavour where the total concentration of flavour proprietary excipient formulations

			containing parsley herb dry must not be more than 5% of the total medicine; or (c) parsley herb dry is used as an excipient in a fragrance where the total concentration of fragrance proprietary excipient formulations containing parsley herb dry must not be more than 1% of the total medicine.
3703	PARSLEY HERB OIL	A, E, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. The following warning statement is required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant.' unless when: (a) parsley herb oil is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) parsley herb oil is used as an excipient in a flavour where the total concentration of flavour proprietary excipient formulations containing parsley herb oil must not be more than 5% of the total medicine; or (c) parsley herb oil is used as an excipient in a fragrance where the total concentration of fragrance proprietary excipient formulations containing parsley herb oil must not be more than 1% of the total medicine.

3704	PARSLEY HERB POWDER	A, E, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. The following warning statement is required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant.' unless when: (a) parsley herb powder is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) parsley herb powder is used as an excipient in a flavour where the total concentration of flavour proprietary excipient formulations containing parsley herb powder must not be more than 5% of the total medicine; or (c) parsley herb powder is used as an excipient in a fragrance where the total concentration of fragrance proprietary excipient formulations containing parsley herb powder must not be more than 1% of the total medicine.
3705	PARSLEY SEED OIL	A, E, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. The following warning statement is required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant.'

			unless when: (a) parsley seed oil is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) parsley seed oil is used as an excipient in a flavour where the total concentration of a flavour proprietary excipient formulations containing parsley seed oil must not be more than 5% of the total medicine; or (c) parsley seed oil is used as an excipient in a fragrance where the total concentration of fragrance excipient formulations containing parsley seed oil must not be more than 1% of the total medicine.
3706	PARTHENOCISSUS TRICUSPIDATA	A, H	
3707	PARTIALLY DEHYDRATED LIQUID SORBITOL	E	Sorbitol is a mandatory component of partially dehydrated liquid sorbitol. Permitted for use only as part of the capsule in medicines where the dosage form is a soft capsule.
3708	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%.
3709	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 0.00002%.
3710	PASPALUM NOTATUM	A, H	

3711	PASSIFLORA CAERULEA	A, H	
3712	PASSIFLORA EDULIS	E	
3713	PASSIFLORA HERB DRY	A, H	
3714	PASSIFLORA INCARNATA	A, E, H	
3715	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%.
3716	PATENT BLUE V	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3717	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3718	PATRINIA SCABIOSIFOLIA	A, H	
3719	PATRINIA VILLOSA	A, H	
3720	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana. 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%. When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine. 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%. 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. 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.’ 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 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).
3721	PAULLINIA PINNATA	A, H	
3722	PAWPAW	E	
3723	PEA	E	
3724	PEA STARCH	E	
3725	PEACH	E	
3726	PEAR	E	
3727	PECAN	E	
3728	PECTIN	A, E	
3729	PEDIOCOCCUS PENTOSACEUS	A	Until 19 September 2027, Pediococcus pentosaceus must only be used in a medicine where: (a) AB-Biotics SA (Client ID 80529) is the sponsor of the medicine (the primary sponsor); or (b) another person is the sponsor of the medicine (the secondary sponsor) and the TGA has been notified that the secondary sponsor has been authorised by the primary sponsor to use the ingredient in the medicine. Only permitted for use in medicines: (a) limited to oral routes of administration; and (b) when the strain of Pediococcus pentosaceus is confirmed to be Colección Española de Cultivos Tipo (CECT) accession number 8330. The strain of Pediococcus pentosaceus must be declared on the label. The maximum recommended daily dose of the medicine must not provide more than 0.5 billion cfu of Pediococcus pentosaceus. The recommended duration of use for a medicine containing

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			Pediococcus pentosaceus must be limited to 21 days or less. Medicines that contain Pediococcus pentosaceus must only be indicated for use in individuals aged 2 weeks and older. The following warning statements (or words to the same effect) must be included on the medicine label: - (ANTIBI2) 'Consult your health professional before taking this medicine with antibiotics'; and - (IMMUNO2) 'May not be suitable for someone taking immunomodulators. Consult your health professional before taking with other medicines'.
3730	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%.
3731	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3732	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3733	PEG-12 DILAURATE	E	
3734	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%.

3735	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3736	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3737	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3738	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3739	PEG-20 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 in the medicine must be no more than 0.5%.
3740	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3741	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3742	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3743	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3744	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 - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3745	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3746	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3747	PEG-35 CASTOR OIL	E	
3748	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3749	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%.
3750	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3751	PEG-40 CASTOR OIL	E	
3752	PEG-40 HYDROGENATED CASTOR OIL	E	
3753	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%.
3754	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3755	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3756	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3757	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3758	PEG-55 PROPYLENE GLYCOL OLEATE	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 0.6%.
3759	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3760	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%.
3761	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%.
3762	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3763	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3764	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3765	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3766	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3767	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%.
3768	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%.
3769	PEG-8 DILAURATE	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%.
3770	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3771	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.
3772	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3773	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3774	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%.
3775	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%.
3776	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.

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			The concentration in the medicine must be no more than 5%.
3777	PELARGONIUM GRAVEOLENS	A, E, H	
3778	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%.
3779	PELTIGERA CANINA	A, H	
3780	PENICILLIUM EXPANSUM	A, H	
3781	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 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.
3782	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%
3783	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%.
3784	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3785	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%.
3786	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%.
3787	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%.

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3788	PENTYLENE GLYCOL	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%.
3789	PEPPER BLACK	E, H	
3790	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%.
3791	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 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.
3792	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 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.
3793	PEPPERMINT LEAF POWDER	A, E, H	Menthol is a mandatory component of peppermint leaf powder. 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 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.
3794	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 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.
3795	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 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.
3796	PEPPERMINT OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient 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 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.
3797	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3798	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%.
3799	PERILLA FRUTESCENS	A, E, H	
3800	PERILLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3801	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%.
3802	PERMETHRIN	E	The total concentration of permethrin in the medicine must not be more than 2%.
3803	PERSEA AMERICANA	A, E, H	
3804	PERSIC OIL	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Persic oil. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
3805	PERSICARIA CHINENSIS	A, H	
3806	PERSICARIA TINCTORIA	A, H	
3807	PERU BALSAM	A, E, H	

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3808	PERU BALSAM OIL	A, E, H	
3809	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%.
3810	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%.
3811	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 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%.
3812	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.
3813	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%.
3814	PETROSELINUM CRISPUM	A, E, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. The following warning statement is required on the medicine label: - (PREGNT2) ‘Do not use if pregnant or likely to become pregnant.’ unless when: (a) Petroselinum crispum is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) Petroselinum crispum is used as an excipient where the total concentration of flavour proprietary excipient formulations containing Petroselinum crispum must not be more than 5% of the total medicine; or (c) Petroselinum crispum is used as an excipient in a fragrance where the total concentration of

			fragrance proprietary excipient formulations containing Petroselinum crispum must not be more than 1% of the total medicine.
3815	PEUCEDANUM PRAERUPTORUM	A, E, H	
3816	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 boldus).
3817	PHALARIS ARUNDINACEA	A, H	
3818	PHALARIS CANARIENSIS	A, H	
3819	PHASEOLUS COCCINEUS	A, H	
3820	PHASEOLUS VULGARIS	A, H	
3821	PHELLINUS ROBINIAE	A, E, H	
3822	PHELLODENDRON AMURENSE	A, E, H	
3823	PHELLODENDRON CHINENSE	A, H	
3824	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3825	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%.
3826	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3827	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%.
3828	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%.
3829	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%
3830	PHENETHYL ISOAMYL ETHER	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 a medicine must be no more than 1%.

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3831	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%.
3832	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%.
3833	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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3834	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%.
3835	PHENOL	E	Only for use in topical medicines for dermal application. The concentration of phenol in the medicine must be no more than 1%.
3836	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%.
3837	PHENOXYETHANOL	E	The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2025; and - released for supply before 1 March 2026. (a) Only for use in topical medicines for dermal application. (b) The concentration of phenoxyethanol in the preparation must not exceed 15%. The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. (c) Only for use in topical medicines for dermal application

			and not to be included in medicines intended for use in the eye. (d) The concentration of phenoxyethanol in the preparation must not exceed 1%.
3838	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%.
3839	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
3840	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3841	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3842	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 medicine must be no more 1%.
3843	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%.
3844	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%.
3845	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%.
3846	PHENYLALANINE	A, E	When the maximum recommended daily dose of the medicine provides more than 500 mg phenylalanine, the following warning statement is required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.
3847	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).
3848	PHENYLETHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3849	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%.
3850	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%.

3851	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%.
3852	PHENYLETHYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3853	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%.
3854	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%.

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3855	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 1%.
3856	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%.
3857	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%.
3858	PHLEUM PRATENSE	A, H	Only permitted in preparations other than phleum pratense pollen extract.
3859	PHLOXINE B	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3860	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3861	PHOENIX DACTYLIFERA	A, E, H	
3862	PHOSPHATIDYL CHOLINE	E	
3863	PHOSPHOLIPIDS	E	Only for use in topical medicines for dermal application and not intended for use in the eye. The concentration in the medicine must be no more than 20%.

3864	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3865	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient. The total concentration of phosphorus in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.
3866	PHOTINIA SERRULATA	A, H	
3867	PHRAGMITES AUSTRALIS	A, H	
3868	PHYLLANTHUS AMARUS	A, H	
3869	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
3870	PHYLLOSTACHYS NIGRA	A, E, H	
3871	PHYSALIS ALKEKENGI	A, H	
3872	PHYSALIS PUBESCENS	A, H	
3873	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
3874	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%.
3875	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3876	PHYTOMENADIONE	A, E	

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3877	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%.
3878	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%.
3879	PICEA ABIES	A, H	
3880	PICEA MARIANA	A, H	
3881	PICRASMA EXCELSA	A, E, H	
3882	PICRORRHIZA KURROA	A, E, H	
3883	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%.
3884	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%.
3885	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%.

3886	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3887	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3888	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3889	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3890	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.
3891	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3892	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3893	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.
3894	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%.
3895	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%.

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3896	PILOCARPUS PINNATIFOLIUS	A, H	Pilocarpine is a mandatory component of Pilocarpus pinnatifolius. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3897	PIMENTA FRUIT OIL	A, E, H	
3898	PIMENTA LEAF OIL	A, E, H	
3899	PIMENTA OFFICINALIS	A, E, H	
3900	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) - (NTAKEN) 'Not to be taken'.
3901	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 not be more than 50 millilitres; and b) a restricted flow insert 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).
3902	PIMPINELLA SAXIFRAGA	A, E, H	
3903	PINE NEEDLE OIL SCOTCH	A, E, H	
3904	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%.
3905	PINE OIL AROMATIC	A, E, H	
3906	PINE OIL PUMILIO	A, E, H	
3907	PINEAPPLE	E	
3908	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%.
3909	PINELLIA TERNATA	A, H	
3910	PINUS CONTORTA	A, E, H	

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3911	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%.
3912	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%.
3913	PINUS MONTICOLA	A, E, H	
3914	PINUS MUGO	A, E, H	
3915	PINUS PALUSTRIS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3916	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%.
3917	PINUS PONDEROSA	A, E, H	
3918	PINUS RADIATA	A, E, H	
3919	PINUS STROBUS	A, E, H	
3920	PINUS SYLVESTRIS	A, E, H	
3921	PINUS TABULIFORMIS	A, E, H	
3922	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%.
3923	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%.
3924	PIPER CHABA	A, E, H	
3925	PIPER CUBEBA	A, E, H	
3926	PIPER KADSURA	A, E, H	
3927	PIPER LONGUM	A, E, H	
3928	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'. 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.
3929	PIPER NIGRUM	A, E, H	
3930	PIPER SARMENTOSUM	A, E, H	
3931	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 not be more than 5% and the concentration of piperine in the medicine must not be more than 0.15%.
3932	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%.

3933	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%.
3934	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%.
3935	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application.
3936	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.
3937	PISCIDIA PISCIPULA	A, E, H	
3938	PISTACIA LENTISCUS	A, E, H	
3939	PISUM SATIVUM	A, E, H	
3940	PLACENTA	H	Only for use as an active homoeopathic ingredient.

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3941	PLANTAGO AFRA	A, E, H	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).
3942	PLANTAGO ARENARIA	A, H	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).
3943	PLANTAGO ASIATICA	A, H	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).
3944	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' 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).
3945	PLANTAGO MAJOR	A, E, H	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).

3946	PLANTAGO OVATA	A, H	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).
3947	PLANTAGO SEED DRY	A, H	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).
3948	PLATANUS OCCIDENTALIS	A, E, H	
3949	PLATANUS RACEMOSA	A, H	
3950	PLATANUS × HISPANICA	A, H	
3951	PLATYCODON GRANDIFLORUS	A, E, H	
3952	PLECTRANTHUS BARBATUS	A, E, H	
3953	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%.
3954	PLUM	E	
3955	PLUMBAGO EUROPAEA	A, H	
3956	PLUMERIA ALBA	A, E, H	
3957	PLUMERIA RUBRA	A, E, H	
3958	POA NEMORALIS	A, H	
3959	POA PRATENSIS	A, H	
3960	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%.
3961	POGOSTEMON CABLIN	A, E, H	
3962	POLACRILIN	E	
3963	POLACRILIN POTASSIUM	E	
3964	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: - (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).
3965	POLIGLUSAM	A, E	The average molecular mass of poliglusam must be greater than 2 kilodaltons. When for internal use: (a) the maximum recommended daily dose of the medicine must not provide more than 1750 milligrams poliglusam; and

			(b) the following warning statement is 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). When for internal use and the dosage form is a powdered preparation, the following warning statement is required 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 medicines for dermal application.
3966	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	When for oral use: (a) the maximum recommended daily dose of the medicine must not provide more than 2000 mg of Poliglusam derived from Aspergillus niger; (b) the following warning statement (or words to the same effect) is 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.'; and (c) if the medicine is a powdered dosage form, the following warning statement is also required on the medicine label: - (DNTPOW) '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.
3967	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%. 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.
3968	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).
3969	POLOXAMER	E	Only for use in topical medicines for dermal application.
3970	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%.
3971	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 2%.
3972	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%.
3973	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.

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			The concentration in the medicine must be no more than 2%.
3974	POLYACRYLATE DISPERSION (30 PER CENT)	E	Methyl methacrylate is a mandatory component of polyacrylate dispersion (30 per cent). The total concentration of methyl methacrylate as residual monomer in the medicine must not be more than 1%. The route of administration for medicines that contain polyacrylate dispersion (30 per cent) must be limited to oral use. Polyacrylate dispersion (30 per cent) is not permitted for use in children under the age of 4 years. The maximum recommended daily dose of the medicine must not provide more than: a) 1.33 grams of polyacrylate dispersion (30 per cent) to individuals aged 4 to 17 years (inclusive); and b) 4.67 grams of polyacrylate dispersion (30 per cent) to individuals aged 18 years and above.
3975	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%.
3976	POLYACRYLIC ACID	E	
3977	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.

3978	POLYAMINOPROPYL BIGUANIDE	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%.
3979	POLYBUTADIENE	E	Only for use as part of an adhesive in topical medicines for dermal application.
3980	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3981	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%.
3982	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%.
3983	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%.
3984	POLYDEXTROSE	E	
3985	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%.

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3986	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%
3987	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%.
3988	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%.
3989	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%.
3990	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%.
3991	POLYETHYLENE	E	
3992	POLYGALA CHINENSIS	A, H	
3993	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.
3994	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
3995	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
3996	POLYGLYCERYL-10 PENTASTEARATE	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%.
3997	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%.
3998	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%.
3999	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
4000	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 medicine must not be more than 3%.

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4001	POLYGLYCERYL-2 ISOSTEARATE	E	Polyglyceryl-2 isostearate must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin or in the eye. The concentration in the medicine must be no more than 2.5%.
4002	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%.
4003	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
4004	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%.
4005	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4006	POLYGLYCERYL-3 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 0.5%.

4007	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%.
4008	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%.
4009	POLYGLYCERYL-3 POLYRICINOLEATE	E	
4010	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%.
4011	POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE	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%.
4012	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%.
4013	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.

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4014	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%.
4015	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
4016	POLYGONATUM MULTIFLORUM	A, H	
4017	POLYGONATUM OFFICINALE	A, H	
4018	POLYGONATUM SIBIRICUM	A, E, H	
4019	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%.
4020	POLYGONUM BISTORTA	A, H	
4021	POLYGONUM ODORATUM	A, H	
4022	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
4023	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.

4024	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
4025	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%.
4026	POLYMETHACRYLIC ACID	E	
4027	POLYMETHYL METHACRYLATE	E	Methyl methacrylate is a mandatory component of polymethyl methacrylate. Only for use in topical medicines for dermal application. The total concentration of methyl methacrylate as residual monomer in the medicine must not be more than 1%.
4028	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%.
4029	POLYPORUS UMBELLATUS	A, H	
4030	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
4031	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 medicine must be no more than 5%.

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			When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
4032	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
4033	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4034	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%.
4035	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
4036	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
4037	POLYQUATERNIUM-37	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4038	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%.
4039	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%.
4040	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%.
4041	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
4042	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%
4043	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%.
4044	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).
4045	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%.
4046	POLYSORBATE 20	E	
4047	POLYSORBATE 40	E	
4048	POLYSORBATE 60	E	
4049	POLYSORBATE 65	E	
4050	POLYSORBATE 80	E	
4051	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4052	POLYSTYRENE	E	Only for use as part of an adhesive in topical medicines for dermal application.
4053	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%.
4054	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 6% in non-spray applications.
4055	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%.
4056	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4057	POLYVINYL ACETATE PHTHALATE	E	
4058	POLYVINYL ALCOHOL	E	
4059	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4060	POMEGRANATE	E	
4061	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4062	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.
4063	PONGAMOL	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%.
4064	PONTEDERIA CRASSIPES	A, H	
4065	POPPY SEED	E, H	
4066	POPPY SEED OIL	E, H	
4067	POPULUS ALBA	A, H	
4068	POPULUS BALSAMIIFERA	A, E, H	
4069	POPULUS CANDICANS	A, H	
4070	POPULUS DELTOIDES	A, H	
4071	POPULUS NIGRA	A, H	

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4072	POPULUS TREMULA	A, H	
4073	POPULUS TREMULOIDES	A, H	
4074	PORCINE	H	Only for use as an active homoeopathic ingredient.
4075	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%.
4076	PORTULACA OLERACEA	A, E, H	
4077	POTABLE WATER	E	
4078	POTASSIUM ACETATE	E	
4079	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4080	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4081	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4082	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4083	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.
4084	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.
4085	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 aspartate monohydrate. The percentage of potassium from potassium aspartate monohydrate should be calculated based on the molecular weight of potassium aspartate monohydrate.
4086	POTASSIUM BICARBONATE	E	
4087	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient. The total concentration of potassium bromide in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4088	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.
4089	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4090	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:

			- 'If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and (c) except when the medicine is for use as oral rehydration therapy, the amount of potassium chloride per dosage unit must not be more than 550 mg. Medicines containing potassium chloride 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 following warning statements are required on the medicine label: - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration of potassium chloride in the medicine must not be more than 3.75%.
4091	POTASSIUM CITRATE	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 citrate.
4092	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%.
4093	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%.
4094	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4095	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.
4096	POTASSIUM GLYCEROPHOSPHATE	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 glycerophosphate.
4097	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.

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			When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4098	POTASSIUM HYDROXYCITRATE	A, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. When for oral use, the following warning statement is required on the medicine label: - (PHLIVER) 'In very rare cases, potassium hydroxycitrate may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.' Medicines containing potassium hydroxycitrate must not be directed for use in children, or in pregnant or lactating women.
4099	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.
4100	POTASSIUM IODIDE	A, E, H	Iodine is a mandatory component of potassium iodide.

			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 contain less than 300 micrograms of iodine. When for external use, the concentration of iodine in the medicine (excluding salt derivatives or iodophors) must not exceed 2.5%.
4101	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%.
4102	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%.
4103	POTASSIUM NITRATE	A, H	Only for dental use. The concentration in the medicine must be no more than 5%.
4104	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.
4105	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%.
4106	POTASSIUM SORBATE	E	
4107	POTASSIUM STANNATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4108	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4109	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.
4110	POTATO STARCH	E	
4111	POTENTILLA ANSERINA	A, H	
4112	POTENTILLA CHINENSIS	A, H	
4113	POTENTILLA DISCOLOR	A, H	
4114	POTENTILLA ERECTA	A, E, H	

4115	POTENTILLA REPTANS	A, H	
4116	POTERIUM OFFICINALE	A, E, H	
4117	POTERIUM SANGUISORBA	A, H	
4118	POVIDONE	E	
4119	POWDERED CELLULOSE	E	
4120	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%.
4121	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%.
4122	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%.
4123	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%.
4124	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%.

4125	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4126	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%.
4127	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4128	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%.
4129	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4130	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%.
4131	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4132	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4133	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4134	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%.
4135	PREGELATINISED MAIZE STARCH	E	
4136	PREGELATINISED POTATO STARCH	E	
4137	PREGELATINISED RICE STARCH	E	
4138	PREGELATINISED STARCH	E	
4139	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4140	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%.
4141	PRICKLY ASH BARK DRY	A, H	
4142	PRICKLY ASH BARK POWDER	A, H	
4143	PRIMULA VERIS	A, E, H	
4144	PRIMULA VULGARIS	A, E, H	
4145	PRINSEPIA UNIFLORA	A, H	
4146	PROBOSCIDEA PARVIFLORA	A, H	
4147	PROGESTERONE	H	Only for use as an active homoeopathic ingredient. The total concentration of progesterone in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.

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4148	PROLINE	A, E	
4149	PROPAN-1-OL	E	Only for use in: - topical medicines for dermal 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%.
4150	PROPANE	E	Only for use as an excipient propellant ingredient.
4151	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%.
4152	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 fragrance concentration in a medicine must be no more 1%.

4153	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%.
4154	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%.
4155	PROPIONYLLEVOCARNITINE HYDROCHLORIDE	A, H	
4156	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: 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

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			irritation or swelling of the mouth or throat occurs, discontinue use.'
4157	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.'
4158	PROPOLIS DRY EXTRACT	A, E	Lead is a mandatory component of Propolis dry 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: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'

4159	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: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4160	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.'
4161	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: 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.'
4162	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%.
4163	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%.
4164	PROPYL GALLATE	E	
4165	PROPYL HYDROXYBENZOATE	E	
4166	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4167	PROPYLENE GLYCOL	E	

4168	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%.
4169	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%.
4170	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 medicine must be no more than 1%.
4171	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4172	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4173	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4174	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%.
4175	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.

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4176	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4177	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4178	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4179	PROSOPIS JULIFLORA	A, H	
4180	PROTEASE	A	Must be derived from Aspergillus oryzae or Aspergillus niger.
4181	PROTEIN HYDROLYSATE	E	
4182	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%.
4183	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 medicine must be no more than 5%.
4184	PRUNELLA VULGARIS	A, H	
4185	PRUNUS AFRICANA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus africana. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.

4186	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 not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4187	PRUNUS AVIUM	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus avium. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4188	PRUNUS CERASIFERA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4189	PRUNUS CERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasus. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.

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4190	PRUNUS DOMESTICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4191	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 not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4192	PRUNUS HUMILIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus humilis. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4193	PRUNUS JAPONICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus japonica. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.

4194	PRUNUS LAUROCERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4195	PRUNUS MUME	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus mume. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4196	PRUNUS PERSICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus persica. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4197	PRUNUS SALICINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.

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4198	PRUNUS SEROTINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus serotina. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4199	PRUNUS SPINOSA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
4200	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4201	PSEUDOCYDONIA SINENSIS	A, H	
4202	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4203	PSEUDOTSUGA MENZIESII	A, H	
4204	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4205	PSIDIUM GUAJAVA	A, E, H	
4206	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4207	PSYLLIUM HUSK DRY	A, H	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).

4208	PSYLLIUM HUSK POWDER	A, E, H	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).
4209	PSYLLIUM SEED DRY	A, E, H	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).
4210	PTELEA TRIFOLIATA	A, H	
4211	PTEROCARPUS MARSUPIUM	A, H	
4212	PTEROCARPUS SANTALINUS	A, E, H	
4213	PUERARIA LOBATA	A, E, H	
4214	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4215	PULLULAN	E	
4216	PUMICE	E	
4217	PUMPKIN	E	
4218	PUMPKIN SEED OIL	E, H	
4219	PUNICA GRANATUM	A, E, H	
4220	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4221	PURIFIED HONEY	A, E	When the route of administration is oral, the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).
4222	PURIFIED SILICEOUS EARTH	E, H	
4223	PURIFIED TALC	E	
4224	PURIFIED WATER	E	
4225	PVM/MA COPOLYMER	E	

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4226	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4227	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4228	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4229	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).
4230	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 of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and

			(v) 100 mg of pyridoxine for individuals aged 19 years and older. If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required 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].
4231	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 of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older.

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			If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required 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].'
4232	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 pyridoxine hydrochloride. The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning

			statement is required 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].'
4233	PYROGLUTAMIC ACID	E	
4234	PYROLA DECORATA	A, H	
4235	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%.
4236	PYRROSIA LINGUA	A, H	
4237	PYRROSIA PETIOLOSA	A, H	
4238	PYRROSIA SHEARERI	A, H	
4239	PYRUS COMMUNIS	A, E, H	Beta-arbutin is a mandatory component of Pyrus communis. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-

			arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4240	PYRUS PYRIFOLIA	A, H	Beta-arbutin is a mandatory component of Pyrus pyrifolia. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4241	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%.
4242	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%.

4243	QUASSIA AMARA	A, E, H	
4244	QUASSIA WOOD JAMAICAN DRY	A, H	
4245	QUASSIA WOOD JAMAICAN POWDER	A, H	
4246	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4247	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4248	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4249	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.
4250	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 2.5%.
4251	QUERCETIN	A	
4252	QUERCETIN DIHYDRATE	A	
4253	QUERCUS ACUTISSIMA	A, H	
4254	QUERCUS ALBA	A, E, H	
4255	QUERCUS PALUSTRIS	A, H	
4256	QUERCUS ROBUR	A, H	
4257	QUERCUS RUBRA	A, H	
4258	QUERCUS VIRGINIANA	A, H	

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4259	QUILLAIA DRY	A, H	
4260	QUILLAIA POWDER	A, E, H	
4261	QUILLAJA SAPONARIA	A, H	
4262	QUINCE	E	
4263	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.
4264	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.
4265	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4266	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4267	QUISQUALIS INDICA	A, H	
4268	R-ALPHA LIPOIC ACID	A	
4269	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%.

4270	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 not be more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must not be 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); - (NTAKEN) 'Not to be taken'; and - (BABY4) ‘Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist’ (or words to that effect). 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); - (NTAKEN) 'Not to be taken'; and - (BABY4) ‘Do not apply to infants under 12 months of age

			except on the advice of a doctor or pharmacist' (or words to that effect). 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); - (NTAKEN) 'Not to be taken'; and - (BABY4) 'Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist' (or words to that effect). If the concentration of camphor is more than 2.5%, the nominal capacity of the container must not be more than 25 millilitres.
4271	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%.
4272	RANUNCULUS BULBOSUS	A, H	
4273	RANUNCULUS FICARIA	A, H	
4274	RANUNCULUS TERNATUS	A, H	
4275	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%.
4276	RAPHANUS SATIVUS	A, E, H	When used as an excipient, the plant preparation must be limited to fresh, dry, powder, oil, fresh juice, dry juice, or concentrated juice.
4277	RASPBERRY	E	
4278	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 medicine must be no more than 5%.
4279	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%.
4280	RASPBERRY FRUIT EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4281	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%.
4282	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%.
4283	RAUWOLFIA SERPENTINA DRY	A, H	The concentration of Rauwolfia Serpentina Dry in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4284	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%.
4285	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%.
4286	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%.
4287	RED ANT	H	Only for use as an active homoeopathic ingredient.
4288	RED CLOVER FLOWER DRY	A, H	
4289	RED CLOVER FLOWER POWDER	A, H	
4290	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4291	RED DEER	A	

4292	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4293	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4294	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4295	REFINED BUGLOSSOIDES ARVENSIS SEED OIL	A	Stearidonic acid is a mandatory component of refined Buglossoides arvensis seed oil. The route of administration for medicines that contain refined Buglossoides arvensis seed oil must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 500 mg of stearidonic acid. The following warning statement (or words to that effect) is required on the medicine label: - (NTAKEN3) 'Not to be taken by children under 3 years old'.
4296	REHMANNIA GLUTINOSA	A, E, H	
4297	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%.
4298	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%.

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4299	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%.
4300	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’.
4301	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 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.'
4302	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 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.’
4303	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 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.’
4304	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4305	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%.
4306	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). 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'.

4307	RHAMNUS FRANGULA	A, H	Glucofrangulins calculated as glucofrangulin A is a mandatory component of 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 - (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'.
4308	RHATANY ROOT DRY	A, H	
4309	RHATANY ROOT POWDER	A, H	
4310	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 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: - (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'.
4311	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 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’.
4312	RHEUM RHAPONTICUM	A, E, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives 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 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'.
4313	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'; - (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 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'.
4314	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4315	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%.
4316	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%.

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4317	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% ethanol v/v.
4318	RHODODENDRON AUREUM	A, H	
4319	RHODODENDRON FERRUGINEUM	A, H	Beta-arbutin is a mandatory component of Rhododendron ferrugineum. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4320	RHODODENDRON GROENLANDICUM	A, H	
4321	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4322	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 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 recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4323	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 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'.
4324	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, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare

			professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements 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'.
4325	RHUS AROMATICA	A, E, H	
4326	RHUS CHINENSIS	A, H	
4327	RHUS GLABRA	A, E, H	
4328	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4329	RIBES GROSSULARIA	A, E, H	
4330	RIBES NIGRUM	A, E, H	
4331	RIBOFLAVIN	A, E	
4332	RIBOFLAVIN SODIUM PHOSPHATE	A, E	

4333	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4334	RIBOFLAVINE	A, E	
4335	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4336	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4337	RIBOSE	A	Only for use in oral medicines.
4338	RICE	E	
4339	RICE BRAN	E	
4340	RICE BRAN OIL	E	
4341	RICE BRAN WAX	A, E, H	
4342	RICE STARCH	E	
4343	RICE VINEGAR	E	
4344	RICE WINE	E	Ethanol is a mandatory component of rice wine.
4345	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4346	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4347	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.
4348	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4349	ROSA ARVENSIS	A, E, H	
4350	ROSA CANINA	A, E, H	

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4351	ROSA CYMOSA	A, E, H	
4352	ROSA EGLANTERIA	A, E, H	
4353	ROSA GALLICA	A, E, H	
4354	ROSA LAEVIGATA	A, E, H	
4355	ROSA MULTIFLORA	A, E, H	
4356	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%.
4357	ROSA RUGOSA	A, E, H	
4358	ROSA VILLOSA	A, E, H	
4359	ROSA X CENTIFOLIA	A, E, H	
4360	ROSA X DAMASCENA	A, E, H	
4361	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%.
4362	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%.
4363	ROSE FRUIT FRESH	A, E, H	
4364	ROSE HIP	E	
4365	ROSE OIL	A, E, H	
4366	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%.
4367	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 1%.
4368	ROSMARINUS OFFICINALIS	A, E, H	Camphor and cineole are mandatory components of Rosmarinus officinalis except when the plant preparation is an essential oil or distillate. In solid and semi-solid preparations, the concentration of camphor must not be more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must not be more than 2.5%. When the concentration of cineole in the preparation other than essential oils or distillates 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 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'.
4369	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'.

4370	ROYAL JELLY FRESH	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of 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'.
4371	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'.
4372	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4373	RUBIA CORDIFOLIA	A, H	
4374	RUBIA TINCTORUM	A, H	
4375	RUBUS CHINGII	A, H	
4376	RUBUS CORCHORIFOLIUS	A, H	
4377	RUBUS COREANUS	A, E, H	

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4378	RUBUS FRUTICOSUS	A, E, H	
4379	RUBUS IDAEUS	A, E, H	
4380	RUBUS OCCIDENTALIS	A, E, H	
4381	RUBUS PARVIFOLIUS	A, H	
4382	RUBUS ROSIFOLIUS	A, H	
4383	RUDBECKIA HIRTA	A, H	
4384	RUE OIL	A, E, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. When used as an active ingredient: (a) Rue oil must only be used as a homoeopathic ingredient; (b) the routes of administration for medicines that contain rue oil must be limited to: (i) topical for dermal use; and (ii) oral; (c) when the homoeopathic potency of the medicine containing rue oil is 12X or lower, the following warning statement is required on the medicine label: - (PREGNT3) ‘Do not use if pregnant or likely to become pregnant, or during lactation.’; and (d) when the medicine is for dermal use, the following statement is required on the medicine: - (SENS) ‘Application to skin may increase sensitivity to sunlight’ (or words to that effect). When used as an excipient ingredient: (a) the route of administration for medicines that contain rue oil must be limited to topical;

			(b) rue oil must only be included in combination with other permitted ingredients as a fragrance proprietary excipient formulation; (c) the total concentration of fragrance proprietary excipient formulations containing rue oil must not be more than 1% of the total medicine; and (d) the total concentration of rue oil in the medicine must not be more than 0.15%.
4385	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%.
4386	RUMEX ACETOSA	A, H	
4387	RUMEX ACETOSELLA	A, H	
4388	RUMEX CONGLOMERATUS	A, H	
4389	RUMEX CRISPUS	A, E, H	
4390	RUMEX PULCHER	A, H	
4391	RUMEX SCUTATUS	A, H	
4392	RUSCUS ACULEATUS	A, H	
4393	RUTA GRAVEOLENS	A, E, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. When used as an active ingredient: (a) Ruta graveolens must only be used as a homoeopathic ingredient;

			(b) the routes of administration for medicines that contain Ruta graveolens must be limited to: (i) topical for dermal use; and (ii) oral; (c) when the homoeopathic potency of the medicine containing Ruta graveolens is 12X or lower, the following warning statement is required on the medicine label: - (PREGNT3) 'Do not use if pregnant or likely to become pregnant, or during lactation.'; and (d) when the medicine is for dermal use, the following statement is required on the medicine: - (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect). When used as an excipient ingredient: (a) the route of administration for medicines that contain Ruta graveolens must be limited to topical; (b) Ruta graveolens must only be included in combination with other permitted ingredients as a fragrance proprietary excipient formulation; (c) the total concentration of fragrance proprietary excipient formulations containing Ruta graveolens must not be more than 1% of the total medicine; and (d) the total concentration of Ruta graveolens in the medicine must not be more than 0.15%.
4394	RUTOSIDE	A, E	
4395	RUTOSIDE TRIHYDRATE	A, E	

4396	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4397	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.
4398	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%.
4399	SABINENE	E	Sabinene must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing sabinene must not be more than 5% of the total medicine.
4400	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%.
4401	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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4402	SACCHARIN	E	
4403	SACCHARIN SODIUM	E	
4404	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4405	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4406	SACCHAROMYCES CEREVISIAE POLYSACCHARIDES	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%.
4407	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4408	SACCHARUM OFFICINARUM	A, E, H	
4409	SAFFLOWER OIL	A, E, H	
4410	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4411	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%.
4412	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%.
4413	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 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'
4414	SAGE OIL SPANISH	A, E, H	
4415	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%.
4416	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%.
4417	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4418	SALIX ALBA	A, E, H	
4419	SALIX DAPHNOIDES	A, H	
4420	SALIX DISCOLOR	A, H	
4421	SALIX FRAGILIS	A, H	

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4422	SALIX NIGRA	A, H	
4423	SALIX PURPUREA	A, H	
4424	SALSOLA KALI	A, H	
4425	SALVIA CHINENSIS	A, H	
4426	SALVIA FRUTICOSA	A, H	
4427	SALVIA HISPANICA	A, E, H	
4428	SALVIA LAVANDULAEFOLIA	A, H	
4429	SALVIA MILTIORRHIZA	A, H	
4430	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%.
4431	SALVIA SCLAREA	A, E, H	
4432	SAMBUCUS CANADENSIS	A, H	
4433	SAMBUCUS EBULUS	A, H	
4434	SAMBUCUS NIGRA	A, E, H	
4435	SANDALWOOD OIL EAST INDIAN	A, E, H	
4436	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4437	SANICULA EUROPAEA	A, H	
4438	SANTALUM ALBUM	A, E, H	
4439	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.
4440	SAPINDUS MUKOROSSI	A, H	
4441	SAPONARIA OFFICINALIS	A, H	
4442	SAPOSHNIKOVIA DIVARICATA	A, H	
4443	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%.
4444	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 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
4445	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.
4446	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%.
4447	SATUREIA HORTENSIS	A, H	
4448	SATUREIA MONTANA	A, H	
4449	SAUROPUS SPATULIFOLIUS	A, H	

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4450	SAURURUS CHINENSIS	A, H	
4451	SAUSSUREA COSTUS	A, H	
4452	SAVORY OIL SUMMER	A, H	
4453	SAXIFRAGA GRANULATA	A, E, H	
4454	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%.
4455	SCAPHIUM SCAPHIGERUM	A, H	
4456	SCHEFFLERA HEPTAPHYLLA	A, H	
4457	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4458	SCHINUS MOLLE	A, H	
4459	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%.
4460	SCHISANDRA CHINENSIS	A, E, H	
4461	SCHIZONEPETA TENUIFOLIA	A, E, H	
4462	SCHOENOCAULON OFFICINALE	A, H	The maximum recommended daily dose of the medicine must not contain more than the equivalent of 1 mg of the dry herbal material. The concentration of total alkaloids of Schoenocaulon officinale in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4463	SCLAREOL	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%.
4464	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%.
4465	SCLERANTHUS ANNUUS	A, H	
4466	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4467	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%.
4468	SCROPHULARIA NINGPOENSIS	A, H	
4469	SCROPHULARIA NODOSA	A, H	
4470	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4471	SCUTELLARIA BAICALENSIS	A, E, H	
4472	SCUTELLARIA BARBATA	A, H	
4473	SCUTELLARIA LATERIFLORA	A, E, H	
4474	SEA WHIP 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 0.02%.
4475	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%.

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4476	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%.
4477	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.
4478	SEDUM ACRE	A, H	
4479	SELAGINELLA TAMARISCINA	A, H	
4480	SELENICEREUS GRANDIFLORUS	A, E, H	
4481	SELENIUM	H	Only for use as an active 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.'
4482	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.'
4483	SELENOMETHIONINE	A	Selenium is a mandatory component of Selenomethionine for oral and sublingual use. Oral medicines must not contain 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.'
4484	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4485	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.
4486	SEMOLINA	E	
4487	SEMPERVIVUM TECTORUM	A, H	
4488	SENEGA ROOT DRY	A, H	
4489	SENEGA ROOT POWDER	A, H	
4490	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, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements 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'.
4491	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 vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

			- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4492	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 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'.
4493	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 statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended';

			- (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements 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'.
4494	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 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'.
4495	SENNA LEAF DRY	A, H	When for oral or sublingual use, Hydroxyanthracene 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) 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'.
4496	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 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 recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4497	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 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'.

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4498	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 daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as

			laxative, the medicine requires the following warning statements 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'.
4499	SEPIA	H	Only for use as an active homoeopathic ingredient. The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
4500	SEQUOIA SEMPERVIRENS	A, H	
4501	SEQUOIADENDRON GIGANTEUM	A, H	
4502	SERENOA REPENS	A, H	
4503	SERINE	A, E	
4504	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4505	SESAME OIL	A, E, H	
4506	SESAMUM INDICUM	A, E, H	
4507	SETARIA ITALICA	A, H	
4508	SHARK CALCIUM CHONDROITIN SULFATE	A	
4509	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)

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4510	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%.
4511	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4512	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%.
4513	SHARK-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 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.’
4514	SHEA BUTTER	E	
4515	SHEA BUTTER ETHYL ESTERS	E	Shea butter ethyl esters must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin. The total concentration of shea butter ethyl esters in the medicine must not be more than 30%.
4516	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4517	SHELLAC	E	
4518	SHEPHERD'S PURSE HERB DRY	A, H	
4519	SHEPHERD'S PURSE HERB POWDER	A, H	
4520	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%.
4521	SIGESBECKIA ORIENTALIS	A, E, H	
4522	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%.
4523	SILICA DIMETHYL SILYLATE	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%.
4524	SILICA SILYLATE	E	Only for use in topical medicines for dermal application.
4525	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4526	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4527	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).
4528	SILVER	H	Only for use as an active homoeopathic ingredient. When for external use, the total concentration of silver in the medicine must not be more than 1%. When for oral use: (a) the total concentration of silver in the medicine must not be more than 0.3%; and (b) the following warning statement is required on the medicine label: - 'Overuse may stain skin or mouth.' (or words to that effect).
4529	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%.
4530	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4531	SILYBUM MARIANUM	A, E, H	
4532	SIMABA CEDRON	A, H	
4533	SIMETHICONE	E	
4534	SIMMONDSIA CHINENSIS	A, E, H	

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4535	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%.
4536	SINAPIS ARVENSIS	A, H	
4537	SINOMENIUM ACUTUM	A, H	
4538	SIPHONESTEGIA CHINENSIS	A, H	
4539	SIRAITIA GROSVENORII	A, E, H	
4540	SISYMBRIUM OFFICINALE	A, H	
4541	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%.
4542	SKIPJACK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of Skipjack-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 from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
4543	SLIPPERY ELM BARK DRY	A, H	
4544	SLIPPERY ELM BARK POWDER	A, E, H	
4545	SMILAX ARISTOLOCHIIFOLIA	A, H	
4546	SMILAX CHINA	A, H	
4547	SMILAX GLABRA	A, H	
4548	SMILAX OFFICINALIS	A, E, H	
4549	SMILAX ORNATA	A, E, H	
4550	SMOKE EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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4551	SODIUM ACETATE	E	
4552	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%.
4553	SODIUM ACID CITRATE	A, E, H	When sodium acid citrate is used as an active ingredient, only for use in oral medicines.
4554	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%.
4555	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).
4556	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).
4557	SODIUM ALGINATE	E	
4558	SODIUM ASCORBATE	A, E, H	
4559	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%.
4560	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%.
4561	SODIUM BENZOATE	E	
4562	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
4563	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4564	SODIUM BICARBONATE	A, E	When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms. Medicines containing sodium bicarbonate 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 Childrens Fund (UNICEF) in the document 'Expert consultation on oral

			rehydration salts formulation 18 July 2001.' c) the following warning statements are required 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.'
4565	SODIUM BISULFITE	E	
4566	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient. The total concentration of sodium bromide in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4567	SODIUM BUTYRATE	A, E	The route of administration for medicines that contain sodium butyrate must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 1200 mg sodium butyrate. The following warning statement (or words to the same effect) is required on the medicine label: - (ADULT) 'Adults only'.
4568	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4569	SODIUM CALCIUM EDETATE	E	When for oral use, sodium is a mandatory component of sodium calcium edetate.

			Sodium calcium edetate must only be included in medicines when: (a) the route of administration is limited to topical for dermal use; or (b) in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of sodium calcium edetate in the medicine must not exceed 0.32%. The total concentration of flavour proprietary excipient formulations containing sodium calcium edetate must not be more than 5% of the total medicine.
4570	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4571	SODIUM CARBONATE	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.
4572	SODIUM CARBONATE MONOHYDRATE	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.
4573	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%.

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4574	SODIUM CARRAGEENAN	E	
4575	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%.
4576	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4577	SODIUM CHLORIDE	A, E, H	
4578	SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient 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).

4579	SODIUM CITRATE	A, E	When for use as an active ingredient, only for oral use.
4580	SODIUM CITRATE DIHYDRATE	A, E	When for use as an active ingredient, only for oral use.
4581	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%.
4582	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4583	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4584	SODIUM CYCLAMATE	E	
4585	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4586	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%.
4587	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4588	SODIUM ERYTHORBATE	E	
4589	SODIUM ETHYL HYDROXYBENZOATE	E	
4590	SODIUM FLUORIDE	A, E, H	Fluoride is a mandatory component of sodium fluoride.

			The route of administration must be limited to dental. The dosage form must be limited to pastes, powders and/or gels for dental hygiene. When used as an active ingredient, the medicine is subject to the following conditions: (a) only for use in combination with at least one other active ingredient; and (b) the concentration of fluoride ion in the medicine must not be 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.'
4591	SODIUM FUMARATE	E	
4592	SODIUM HYALURONATE	A, E	When for use as an excipient ingredient, sodium hyaluronate must only be used in medicines with a topical route of administration for dermal application. When for use as an active ingredient: (a) the molecular mass of sodium hyaluronate must be between 600 and 1600 kilodaltons; and (b) sodium hyaluronate must only be used in medicines when the route of administration is limited to: (i) topical for dermal application; or (ii) oral.

			When for use in a topical medicine for dermal application the concentration of sodium hyaluronate in the medicine must not exceed 2.0%. When for use as an active ingredient and the route of administration is oral: (a) the maximum recommended daily dose must not provide more than 200 milligrams sodium hyaluronate; (b) the recommended duration of use of the medicine must be limited to three months; and (c) the following warning statements (or words to the same effect) are required on the medicine label : - (ADULT) 'Adults only'; and - (PREGNT) ' Not recommended for use by pregnant and lactating women'.
4593	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4594	SODIUM HYDROXIDE	E	The concentration of sodium hydroxide in the medicine must not be 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.
4595	SODIUM HYDROXYCITRATE	A	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or

			- released for supply on or after 1 March 2026. When for oral use, the following warning statement is required on the medicine label: - (SHLIVER) 'In very rare cases, sodium hydroxycitrate may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.' Medicines containing sodium hydroxycitrate must not be directed for use in children, or in pregnant or lactating women.
4596	SODIUM HYDROXYETHYL ACRYLATE/ACRYLOYLDIMETHYL TAURATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4597	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4598	SODIUM HYPOCHLORITE	E	The pH of the sodium hypochlorite preparation must be less than 11.5.
4599	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4600	SODIUM LACTATE	E	
4601	SODIUM LAURETH SULFATE	E	
4602	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%.

4603	SODIUM LAUROYL LACTYLATE	E	Sodium lauroyl lactylate must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin or in the eye. The concentration in the medicine must be no more than 0.2%.
4604	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 medicine must be no more than 11%.
4605	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4606	SODIUM LAURYL PHOSPHATE	E	
4607	SODIUM LAURYL SULFATE	E	
4608	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4609	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4610	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%.
4611	SODIUM METABISULFITE	E	
4612	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.

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			The concentration in the medicine must not be more than 0.1%.
4613	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine must be no more than 2%.
4614	SODIUM METHYL HYDROXYBENZOATE	E	
4615	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.
4616	SODIUM MONOFLUOROPHOSPHATE	A	Fluoride is a mandatory component of sodium monofluorophosphate. The route of administration must be limited to dental. The dosage form must be limited to pastes, powders and/or gels for dental hygiene. When sodium monofluorophosphate is used as an active ingredient, it is subject to the following conditions: (a) only for use in combination with at least one other active ingredient; and (b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000

			mg/kg, the following warning statements are required 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.'
4617	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%.
4618	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4619	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4620	SODIUM PANTOTHENATE	A, E, H	
4621	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4622	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 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). 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 - (ADULT) 'Adults only' (or words to that effect). 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). 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).
4623	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.

4624	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4625	SODIUM POLYACRYLATE STARCH	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 1%.
4626	SODIUM POLYMETAPHOSPHATE	E	
4627	SODIUM PROPIONATE	E	
4628	SODIUM PROPYL HYDROXYBENZOATE	E	
4629	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%.
4630	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.'
4631	SODIUM SELENATE DECAHYDRATE	A	Selenium is a mandatory component of sodium selenate 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.'
4632	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.’
4633	SODIUM SELENITE PENTAHYDRATE	A	Selenium is a mandatory component of Sodium selenite pentahydrate. 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.’

4634	SODIUM SILICATE	E	
4635	SODIUM STARCH GLYCOLLATE	E	
4636	SODIUM STARCH GLYCOLLATE TYPE A	E	
4637	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4638	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%.
4639	SODIUM STEAROYL GLUTAMATE	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 2.5%.
4640	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4641	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%.
4642	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4643	SODIUM SULFATE	A, E, H	When it is not intended to be a laxative, the following warning statement is required on the medicine label: - (LAX4) 'Substance may have a laxative effect'.

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4644	SODIUM SULFATE DECAHYDRATE	A, E, H	When it is not intended to be a laxative, the following warning statement is required on the medicine label: - (LAX4) 'Substance may have a laxative effect'.
4645	SODIUM SULFITE	E	
4646	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application.
4647	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%.
4648	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.
4649	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.

4650	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%.
4651	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 than 10mg of steroidal alkaloids calculated as solanine.
4652	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.
4653	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.
4654	SOLIDAGO GIGANTEA	A, H	
4655	SOLIDAGO GIGANTEA MIS	A, E, H	
4656	SOLIDAGO VIRGAUREA	A, E, H	
4657	SOLUBLE MAIZE STARCH	E	
4658	SOLUBLE POTATO STARCH	E	

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4659	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4660	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4661	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4662	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%.
4663	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4664	SOPHORA FLAVESCENS	A, E, H	
4665	SOPHORA TONKINENSIS	A, H	
4666	SORBIC ACID	E	
4667	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4668	SORBITAN MONO-OLEATE	E	
4669	SORBITAN MONOLAURATE	E	
4670	SORBITAN MONOSTEARATE	E	
4671	SORBITAN OLEATE	E	
4672	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%.
4673	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%.

4674	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4675	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4676	SORBITAN STEARATE	E	
4677	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4678	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 with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
4679	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.
4680	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 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.
4681	SORBUS AUCUPARIA	A, H	
4682	SORGHUM	E	
4683	SORGHUM VULGARE	A, H	
4684	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid. The maximum recommended daily dose of the medicine must not provide more than 300 mg of soy phosphatidylserine.
4685	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder. The maximum recommended daily dose of the medicine must not provide more than 300 mg of soy phosphatidylserine.
4686	SOY POLYSACCHARIDE	E	
4687	SOY PROTEIN	E	
4688	SOY STEROL	E	
4689	SOYA BEAN	E	
4690	SOYA OIL	A, E, H	
4691	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%.
4692	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%.
4693	SPARGANIUM STOLONIFERUM	A, H	
4694	SPARTIUM JUNCEUM	A, H	
4695	SPATHOLOBUS SUBERECTUS	A, H	
4696	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 concentration of menthol, which can cause severe skin irritation.

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			When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4697	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). 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.
4698	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%.
4699	SPIGELIA ANTHELMIA	A, H	
4700	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4701	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 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.
4702	SPINACH	E	
4703	SPINACIA OLERACEA	A, E, H	

4704	SPIRODELA POLYRRHIZA	A, H	
4705	SPIRULINA	E	
4706	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use as an excipient for oral routes of administration.
4707	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use as an excipient for oral routes of administration.
4708	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%.
4709	SQUALANE	E	Only for use in topical medicines for dermal application.
4710	SQUALENE	A, E	
4711	SQUID OIL	A	Only for use in oral medicines. 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 dosage form for therapeutic use. The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
4712	SQUILL DRY	A, H	
4713	SQUILL INDIAN DRY	A, H	
4714	SQUILL INDIAN POWDER	A, H	
4715	SQUILL POWDER	A, H	
4716	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.'
4717	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.'
4718	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.'
4719	STACHYS OFFICINALIS	A, E, H	
4720	STACHYS PALUSTRIS	A, H	
4721	STACHYURUS HIMALAICUS	A, H	
4722	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%.
4723	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4724	STAR ANISE OIL	A, E	When the total concentration of star anise oil in the medicine is more than 50%:

			(a) the nominal capacity of the container must not be more than 50 mL; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4725	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%.
4726	STARCH SODIUM OCTENYL SUCCINATE	E	
4727	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4728	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4729	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4730	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4731	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4732	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).
4733	STEARETH-10	E	Only for use in topical medicines for dermal application.
4734	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%.
4735	STEARETH-2	E	Only for use in topical medicines for dermal application.
4736	STEARETH-20	E	Only for use in topical medicines for dermal application.
4737	STEARETH-21	E	Only for use in topical medicines for dermal application.
4738	STEARETH-5	E	Only for use in topical medicines for dermal application.
4739	STEARIC ACID	E	
4740	STEAROPTENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4741	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%.
4742	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4743	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4744	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4745	STEARYL ALCOHOL	E	
4746	STEARYL BEHENATE	E	Only for use as an excipient ingredient 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 3.5% in the final formulation.
4747	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 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).
4748	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4749	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.

4750	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%.
4751	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4752	STELLARIA CHAMAEJASME	A, H	
4753	STELLARIA DICHOTOMA	A, H	
4754	STELLARIA MEDIA	A, E, H	
4755	STEMONA JAPONICA	A, H	
4756	STEMONA SESSILIFOLIA	A, H	
4757	STENOTAPHRUM SECUNDATUM	A, H	
4758	STEPHANIA TETRANDA	A, H	
4759	STERCULIA	A, H	
4760	STERCULIA TRAGACANTHA	A, H	
4761	STERCULIA URENS	A, H	
4762	STEVIA REBAUDIANA	A, E, H	
4763	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4764	STILLINGIA SYLVATICA	A, H	
4765	STORAX PREPARED	A, E, H	
4766	STRAWBERRY	E	
4767	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%.
4768	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'.
4769	STREPTOCOCCUS THERMOPHILUS	A	
4770	STROBILANTHES CUSIA	A, H	
4771	STRONG AMMONIA SOLUTION	E	Ammonia is a mandatory component of strong 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%.
4772	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4773	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4774	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4775	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 not be

			more than 1 milligram/Kg or 1 milligram/L or 0.0001%.
4776	STRYCHNOS NUX-VOMICA	A, H	Strychnine (of Strychnos spp.) is a mandatory component of Strychnos nux-vomica. The concentration of Strychnine (of Strychnos spp.) must not be more than 1 milligram/Kg or 1 milligram/L or 0.0001%.
4777	STYPHNOLOBIUM JAPONICUM	A, E, H	
4778	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%.
4779	STYRAX BENZOIN	A, E, H	
4780	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%.
4781	STYRAX PARALLELONEURUM	A, H	
4782	STYRAX TONKINENSIS	A, H	
4783	STYRENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

			The total concentration of styrene in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4784	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4785	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%.
4786	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4787	SUCCINIC ACID	E	
4788	SUCRALOSE	E	
4789	SUCROSE	E	
4790	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%.
4791	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%.
4792	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.

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			The concentration in the medicine must be no more than 2%.
4793	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4794	SUCROSE LAURATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate.
4795	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.
4796	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4797	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).
4798	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.
4799	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%.
4800	SUDAN III	E	Permitted for use only as a colour for topical use.
4801	SUGAR CANE WAX ALCOHOLS	A, H	The routes of administration for medicines that contain sugar cane wax alcohols must be limited to: (a) topical for dermal use; and (b) oral. When for use in topical medicines, the maximum recommended daily dose of the medicine must not provide more than 12 mg of sugar cane wax alcohols. When for oral use: (a) the maximum recommended daily dose of the medicine must not provide more than: (i) 12 mg of sugar cane wax alcohols for individuals aged less than 18 years; and (ii) 20 mg of sugar cane wax alcohols for individuals aged 18 years and above. (b) The following warning statement (or words to the same effect) is required on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women'. (c) If the maximum recommended daily dose of the medicine contains 20 mg of sugar cane wax

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			alcohols, the following warning statement is also required on the medicine label: - (ADULTS) ‘Adults only’.
4802	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of sugarcane.
4803	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4804	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%.
4805	SULFUR DIOXIDE	E	
4806	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4807	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%.
4808	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%.
4809	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.

			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).
4810	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).
4811	SUNFLOWER OIL	A, E, H	
4812	SUNFLOWER SEED	E, H	
4813	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4814	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.

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4815	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4816	SWEDE	E	
4817	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%.
4818	SWEET POTATO	E	
4819	SWERTIA CHIRATA	A, H	
4820	SWIETENIA MAHOGANI	A, H	
4821	SYAGRUS ROMANZOFFIANA	A, E, H	
4822	SYMPHYOTRICHUM NOVI-BELGII	A, H	
4823	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 application, the concentration in the preparation must be no more than 10mg/kg or 10mg/L or 0.001%.
4824	SYMPLOCARPUS FOETIDUS	A, H	
4825	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4826	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.

4827	SYNTHETIC WAX	E	
4828	SYRINGA RETICULATA	A, H	
4829	SYRINGA VULGARIS	A, H	
4830	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 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%.
4831	SYZYGIUM CUMINI	A, H	

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4832	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%.
4833	TABEBUIA SERRATIFOLIA	A, E, H	
4834	TADEHAGI TRIQUETRUM	A, H	
4835	TAGETES ERECTA	A, E, H	When used as an excipient ingredient, only for use 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%.
4836	TAGETES MINUTA	A, E, H	
4837	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%.
4838	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4839	TALLOW	E	Only for use in topical medicines for dermal application.
4840	TALLOW GLYCERIDES	E	
4841	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%.
4842	TAMARIX APHYLLA	A, H	
4843	TAMARIX CHINENSIS	A, H	
4844	TAMARIX GALLICA	A, H	
4845	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.
4846	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4847	TANACETUM COCCINEUM SUBSP. COCCINEUM	A, H	
4848	TANACETUM PARTHENIUM	A, E, H	
4849	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%.
4850	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%.

4851	TANGERINE OIL COLDPRESSED	A, E, H	When used internally, oxedrine is a mandatory component of tangerine oil coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
4852	TANNIC ACID	E	
4853	TAPIOCA STARCH	E	
4854	TARAXACUM MONGOLICUM	A, E, H	
4855	TARAXACUM OFFICINALE	A, E, H	
4856	TARO	E	
4857	TARRAGON OIL	A, E, H	
4858	TARTARIC ACID	E	
4859	TARTRAZINE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4860	TARTRAZINE ALUMINIUM LAKE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4861	TASMANNIA LANCEOLATA	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%.
4862	TAURINE	A, E	
4863	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4864	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'.
4865	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4866	TERMINALIA CATAPPA	A, H	
4867	TERMINALIA CHEBULA	A, H	
4868	TERMINALIA FERDINANDIANA	A, E, H	When used as an active ingredient: (a) the plant part must be from fruit flesh or seed only; and (b) the plant preparation must be limited to fresh, dry, powder. and extraction preparations with water as the only solvent. When used as an excipient ingredient: (a) the route of administration for medicines that contain Terminalia ferdinandiana must be limited to topical for dermal use; (b) medicines that contain Terminalia ferdinandiana are not to be intended for use on damaged skin or in the eye; and (c) the concentration of Terminalia ferdinandiana in the medicine must not be more than 0.3%.
4869	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%.
4870	TERPENE RESIN	E	Terpene resin must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application.
4871	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 fragrance concentration in a medicine must be no more 1%.
4872	TERPINEOL	E	
4873	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%.
4874	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%.
4875	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 medicine must be no more 1%.
4876	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%.
4877	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%.
4878	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.

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4879	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%.
4880	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 flavour concentration in a medicine must be no more than 5%.
4881	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%.
4882	TETRACLINIS ARTICULATA	A, E, H	
4883	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%.
4884	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.
4885	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 medicine must be no more than 1%.
4886	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%.
4887	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%.
4888	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%.
4889	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%.
4890	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%.
4891	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%.
4892	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%.
4893	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 1%.
4894	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%.
4895	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.

4896	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%.
4897	TETRAPANAX PAPYRIFER	A, H	
4898	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4899	TETRASODIUM PYROPHOSPHATE	E	
4900	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4901	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4902	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4903	THAPSIA GARGANICA	A, H	
4904	THAUMATIN	E	
4905	THEANINE	A	Only to be used in a medicine where Trans Chem Pty Ltd (Client ID 21878), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient

			in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 March 2026. The route of administration for medicines that contain theanine must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 450 mg of theanine. The following warning statements (or words to the same effect) are required on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'.
4906	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%.
4907	THEMEDA TRIANDRA	A, H	
4908	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma cacao. 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%. When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine. 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%. 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. 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 80 mg of caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ 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 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).
4909	THEOBROMA OIL	A, E, H	
4910	THIAMINE	A, E	
4911	THIAMINE HYDROCHLORIDE	A, E	
4912	THIAMINE NITRATE	A, E	
4913	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%.
4914	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 0.02%.
4915	THLASPI ARVENSE	A, E, H	
4916	THREONINE	A, E	
4917	THUJA OCCIDENTALIS	A, H	
4918	THUJA PLICATA	A, E, H	
4919	THYME HERB DRY	A, E, H	
4920	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).
4921	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.
4922	THYMOL METHYL ETHER	E	Thymol methyl ether must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of the flavour proprietary excipient formulation containing thymol methyl ether must not be more than 5% of the total medicine.
4923	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 and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4924	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4925	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

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			out of reach of children' (or words to that effect).
4926	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).
4927	THYMUS VULGARIS	A, E, H	When the plant preparation is oil or distillate, and the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4928	THYMUS VULGARIS MIS	A, E, H	When the plant preparation is an oil or distillate, and the concentration of Thymus vulgaris MIS oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label:

			- (CHILD) 'Keep out of reach of children' (or words to that effect).
4929	THYMUS ZYGIS	A, H	When the plant preparation is an oil or a distillate, and the concentration of Thymus zygis oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4930	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4931	TILACTASE	A	Must be derived from Aspergillus oryzae and comply with the relevant USP monograph.
4932	TILIA CORDATA	A, E, H	
4933	TILIA PLATYPHYLLOS	A, E, H	
4934	TILIA TOMENTOSA	A, H	
4935	TILIA X VULGARIS	A, E, H	
4936	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 medicine must be no more than 1%.
4937	TIN	H	Only for use as an active homoeopathic ingredient.
4938	TINOSPORA CORDIFOLIA	A, H	
4939	TINOSPORA SINENSIS	A, H	

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4940	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).
4941	TOCOCYSTEAMIDE	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%.
4942	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%

4943	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%.
4944	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 medicine must be no more than 0.05%
4945	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4946	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%.
4947	TOLU BALSAM	A, E, H	
4948	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%.
4949	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%.
4950	TOLYLALDEHYDE GLYCERYLACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4951	TOMATO	E	
4952	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%.
4953	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%.
4954	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%.

4955	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4956	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.
4957	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4958	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4959	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4960	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). Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4961	TRAGACANTH	A, E	
4962	TRAMETES VERSICOLOR	A, H	

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4963	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4964	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%.
4965	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.
4966	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%.
4967	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%.

4968	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%.
4969	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 5%.
4970	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%.
4971	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%.
4972	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%.
4973	TRANS-2-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4974	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%.
4975	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%.
4976	TRANS-2-OCTENAL	E	trans-2-Octenal must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing trans-2-

			octenal must not be more than 1% of the total medicine.
4977	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%.
4978	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 flavour concentration in a medicine must be no more than 5%.
4979	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%.
4980	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%.
4981	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%.
4982	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 5%.
4983	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of treacle.
4984	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 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%.
4985	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.
4986	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.
4987	TREMELLA FUCIFORMIS	A, H	
4988	TRIACETIN	E	
4989	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4990	TRIADICA SEBIFERA	A, H	
4991	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.
4992	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.

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4993	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%.
4994	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%.
4995	TRIBULUS TERRESTRIS	A, E, H	
4996	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%.
4997	TRICALCIUM PHOSPHATE	E	
4998	TRICAPRYLIN	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%.
4999	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%.
5000	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.

5001	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%.
5002	TRICHODERMA VIRIDE	A, E, H	
5003	TRICHOSANTHES KIRILOWII	A, E, H	
5004	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
5005	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%.
5006	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%.
5007	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
5008	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%.
5009	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 a medicine must be no more than 1%.
5010	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
5011	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%.
5012	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%.
5013	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
5014	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
5015	TRIETHOXYCAPRYLYLSILANE	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 1%.
5016	TRIETHYL CITRATE	E	
5017	TRIETHYLENE GLYCOL	E	
5018	TRIFOLIUM PRATENSE	A, E, H	
5019	TRIFOLIUM REPENS	A, H	

5020	TRIGONELLA FOENUM-GRAECUM	A, E, H	
5021	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%.
5022	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
5023	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
5024	TRIISODECYL TRIMELLITATE	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%.
5025	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%.
5026	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
5027	TRILAURIN	E	Only for use in topical medicines for dermal application.
5028	TRILISA ODORATISSIMA	A, H	
5029	TRILLIUM ERECTUM	A, H	
5030	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%.
5031	TRIMETHYL HYDROXYPENTYL 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%.
5032	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%.
5033	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%.
5034	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%.
5035	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 1%.

5036	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5037	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%.
5038	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5039	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient. The total concentration of trinitrophenol in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5040	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%.
5041	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 medicine must be no more than 12%.
5042	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%.
5043	TRIOSTEUM PERFOLIATUM	A, H	

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5044	TRIOXAUNDECANEDIOIC ACID	E	
5045	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%.
5046	TRIS-BIPHENYL TRIAZINE	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 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).
5047	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%.
5048	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
5049	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 0.2%.
5050	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%.
5051	TRISTEARIN	E	
5052	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.
5053	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.
5054	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%.
5055	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5056	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
5057	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).
5058	TROLLIUS CHINENSIS	A, H	
5059	TROMETAMOL	E	
5060	TROMETAMOL HYDROCHLORIDE	E	
5061	TROPAEOLUM MAJUS	A, E, H	
5062	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5063	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%.
5064	TSUGA CANADENSIS	A, H	
5065	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%.
5066	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.

5067	TURNERA DIFFUSA	A, E, H	Beta-arbutin is a mandatory component of Turnera diffusa. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5068	TURNIP	E	
5069	TURPENTINE OIL	A, E	Only permitted for use when turpentine oil is derived from sources other than mineral turpentine. The concentration in the medicine must not be more than 25%.
5070	TYPHA ANGUSTIFOLIA	A, H	
5071	TYPHA LATIFOLIA	A, H	
5072	TYPHONIUM GIGANTEUM	A, H	
5073	TYROSINE	A, E	