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

This instrument is in 6 volumes:

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

Note: See sections 5 and 6.

Permissible ingredients and requirements

Column 1	Column 2	Column 3	Column 4
Item	**Ingredient name**	**Purpose**	**Specific requirements**
3605	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%.
3606	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%.
3607	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 be no more than

			8%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3608	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%.
3609	PAEONIA LACTIFLORA	A, E, H	
3610	PAEONIA OBOVATA	A, H	
3611	PAEONIA SUFFRUTICOSA	A, E, H	
3612	PAEONIA VEITCHII	A, H	
3613	PALIURUS SPINA-CHRISTI	A, H	
3614	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3615	PALM FRUIT OIL	A, E, H	
3616	PALM GLYCERIDES	E	
3617	PALM KERNEL OIL	A, E, H	
3618	PALM TOCOTRIENOLS COMPLEX	A, H	
3619	PALMARIA PALMATA	A, H	
3620	PALMAROSA OIL	A, E, H	
3621	PALMITIC ACID	E	
3622	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3623	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%.

3624	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%
3625	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%.
3626	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%.
3627	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%.
3628	PANAX GINSENG	A, E, H	

3629	PANAX JAPONICUS	A, H	
3630	PANAX NOTOGINSENG	A, H	
3631	PANAX PSEUDOGINSENG	A, H	
3632	PANAX QUINQUEFOLIUS	A, H	
3633	PANICUM MILIACEUM	A, H	
3634	PANTETHINE	E	Only for use in topical medicines for dermal application.
3635	PANTHENOL	A, E	
3636	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3637	PANTOLACTONE	E	
3638	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3639	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%.
3640	PAPAIN	A, E	
3641	PAPER	E	Only for use in topical medicines for dermal

			application.
3642	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%.
3643	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%.
3644	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%.
3645	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%.
3646	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%.
3647	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%.
3648	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%.

3649	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%.
3650	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%.
3651	PARA-HYDROXYBENZOIC ACID	E	
3652	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%.

3653	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%.
3654	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%.
3655	PARA-METHYL DIMETHYLBENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3656	PARA-PROPYL 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%.
3657	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%.
3658	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%.
3659	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%.
3660	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%.
3661	PARAMERIA LAEVIGATA	A, H	
3662	PARIETARIA JUDAICA	A, H	
3663	PARIS POLYPHYLLA	A, H	
3664	PARIS QUADRIFOLIA	A, H	
3665	PARSLEY	E, H	
3666	PARSLEY HERB DRY	A, E, H	
3667	PARSLEY HERB OIL	A, E, H	
3668	PARSLEY HERB POWDER	A, E, H	
3669	PARSLEY SEED OIL	A, E, H	
3670	PARTHENOCISSUS TRICUSPIDATA	A, H	
3671	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%.

3672	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%.
3673	PASPALUM NOTATUM	A, H	
3674	PASSIFLORA CAERULEA	A, H	
3675	PASSIFLORA EDULIS	E	
3676	PASSIFLORA HERB DRY	A, H	
3677	PASSIFLORA INCARNATA	A, E, H	
3678	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%.
3679	PATENT BLUE V	E	Permitted for use only as a colour for oral and topical use.
3680	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
3681	PATRINIA SCABIOSIFOLIA	A, H	

3682	PATRINIA VILLOSA	A, H	
3683	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana when used for oral ingestion. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
3684	PAULLINIA PINNATA	A, H	
3685	PAWPAW	E	
3686	PEA	E	
3687	PEA STARCH	E	
3688	PEACH	E	

3689	PEANUT	E	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
3690	PEAR	E	
3691	PECAN	E	
3692	PECTIN	A, E	
3693	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%.
3694	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3695	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3696	PEG-12 DILAURATE	E	
3697	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%.
3698	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3699	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3700	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3701	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3702	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%.
3703	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.

3704	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3705	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3706	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3707	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 be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following

			statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3708	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3709	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3710	PEG-35 CASTOR OIL	E	
3711	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3712	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%.
3713	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3714	PEG-40 CASTOR OIL	E	
3715	PEG-40 HYDROGENATED CASTOR OIL	E	
3716	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%.
3717	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3718	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3719	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal

			application.
3720	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3721	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%.
3722	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3723	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%.
3724	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%.
3725	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3726	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3727	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3728	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3729	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3730	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%.

3731	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%.
3732	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%.
3733	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3734	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.

3735	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3736	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3737	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%.
3738	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%.
3739	PEG/PPG-18/18 DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3740	PELARGONIUM GRAVEOLENS	A, E, H	
3741	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%.
3742	PELTIGERA CANINA	A, H	
3743	PENICILLIUM EXPANSUM	A, H	
3744	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.
3745	PENTAERYTHRITYL TETRA-DI-T-BUTYL	E	Only for use in topical medicines for dermal application and not to be

	HYDROXYHYDROCINNAMATE		included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.018%
3746	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%.
3747	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3748	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%.
3749	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%.
3750	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%.
3751	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%.
3752	PEPPER BLACK	E, H	
3753	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%.
3754	PEPPER WHITE	E, H	

3755	PEPPERMINT AMERICAN EXT.	E	Menthol is a mandatory component of peppermint american ext. When the medicine is for topical use: a) the medicine must not be intended for use in the eye or on damaged skin; b) the maximum concentration of menthol must not exceed 5%; and c) 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; and - (EYE) Avoid contact with eyes (or words to that effect). When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3756	PEPPERMINT LEAF DRY	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements

			under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of peppermint leaf dry. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) 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; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3757	PEPPERMINT LEAF POWDER	A, E, H	When the ingredient is included in a medicine that is

		listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of peppermint leaf powder. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) 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; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum

			recommended daily dose must not contain more than 1 gram of menthol.
3758	PEPPERMINT OIL	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018, and supplied on or after 1 January 2020 the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of peppermint oil. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) 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; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3759	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: a) the medicine must not be intended for use in the eye or on damaged skin; b) the maximum concentration of menthol must not exceed 5%; and c) 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; and - (EYE) Avoid contact with eyes (or words to that effect). When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3760	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: a) the medicine must not be intended for use in the eye or on damaged skin; b) the maximum concentration of menthol must not exceed 5%; and c) 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; and - (EYE) Avoid contact with eyes (or words to that effect). When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3761	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3762	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%.
3763	PERILLA FRUTESCENS	A, E, H	Rosmarinic acid and vicenin-2 are only permitted for use if the plant part of Perilla frutescens is leaf.

3764	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%.
3765	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%.
3766	PERMETHRIN	E	The concentration of in the medicine must be no more than 2%.
3767	PERSEA AMERICANA	A, E, H	
3768	PERSIC OIL	A, E, H	Amygdalin and Hydrocyanic acid are mandatory components of Persic oil. The concentration of amygdalin in the medicine must be no more than 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1

			microgram/L or 0.0000001%.
3769	PERSICARIA CHINENSIS	A, H	
3770	PERSICARIA TINCTORIA	A, H	
3771	PERSIMMON	E	
3772	PERU BALSAM	A, E, H	
3773	PERU BALSAM OIL	A, E, H	
3774	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%
3775	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%.
3776	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%.
3777	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.
3778	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%.
3779	PETROSELINUM CRISPUM	A, E, H	
3780	PEUCEDANUM PRAERUPTORUM	A, E, H	
3781	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).
3782	PHALARIS ARUNDINACEA	A, H	
3783	PHALARIS CANARIENSIS	A, H	
3784	PHASEOLUS COCCINEUS	A, H	
3785	PHASEOLUS VULGARIS	A, H	
3786	PHELLINUS ROBINIAE	A, E, H	
3787	PHELLODENDRON AMURENSE	A, E, H	
3788	PHELLODENDRON CHINENSE	A, H	
3789	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3790	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%.
3791	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%.
3792	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%.
3793	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%.
3794	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%
3795	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%.
3796	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%.
3797	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%.
3798	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%.
3799	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%.
3800	PHENOL	E	Only for use in topical

			medicines for dermal application. The concentration of phenol in the medicine must be no more than 1%.
3801	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%.
3802	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The concentration of phenoxyethanol in the preparation must not exceed 15%.
3803	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%.

3804	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
3805	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3806	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3807	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%.
3808	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%.

3809	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%.
3810	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%.
3811	PHENYLALANINE	A, E	When for oral ingestion the medicine requires the following warning statement on the medicine label: - (PKU) 'Phenylketonurics are warned that this medicine contains phenylalanine' (or words to that effect). When the medicine contains more than 500mg in the maximum recommended daily dose it requires the following warning statement on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become

			pregnant'.
3812	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 be no more than 4%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or

			words to this effect).
3813	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%.
3814	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%.
3815	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%.
3816	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%.
3817	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%.
3818	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%.
3819	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%.
3820	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%.
3821	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%.
3822	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%.
3823	PHLEUM PRATENSE	A, H	
3824	PHLOXINE B	E	Permitted for use only as a colour for oral and topical use.
3825	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.

3826	PHOENIX DACTYLIFERA	A, E, H	
3827	PHOSPHATIDYL CHOLINE	E	
3828	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%.
3829	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3830	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient.
3831	PHOTINIA SERRULATA	A, H	
3832	PHRAGMITES AUSTRALIS	A, H	
3833	PHYLLANTHUS AMARUS	A, H	
3834	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application. When ascorbic acid is claimed as a component the plant part is restricted to fruit.
3835	PHYLLOSTACHYS NIGRA	A, E, H	

3836	PHYSALIS ALKEKENGI	A, H	
3837	PHYSALIS PUBESCENS	A, H	
3838	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
3839	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%.
3840	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3841	PHYTOMENADIONE	A, E	
3842	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%.
3843	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%.
3844	PICEA ABIES	A, H	
3845	PICEA MARIANA	A, H	
3846	PICRASMA EXCELSA	A, E, H	
3847	PICRORRHIZA KURROA	A, E, H	
3848	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%.
3849	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%.
3850	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%.
3851	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3852	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3853	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3854	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3855	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.
3856	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3857	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3858	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.

3859	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%.
3860	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%.
3861	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%.
3862	PIMENTA FRUIT OIL	A, E, H	
3863	PIMENTA LEAF OIL	A, E, H	
3864	PIMENTA OFFICINALIS	A, E, H	
3865	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'.
3866	PIMPINELLA ANISUM	A, E, H	When the plant preparation for Pimpinella anisum is an oil or distillate and the concentration of this oil or distillate in the medicine is more than 50%: a) the nominal capacity of the container must be no more than 50 millilitres; and b) a restricted flow insert is must be fitted on the container; and c) the medicine requires the following warning statement on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or words to that effect).

3867	PIMPINELLA SAXIFRAGA	A, E, H	
3868	PINE NEEDLE OIL SCOTCH	A, E, H	
3869	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%.
3870	PINE OIL AROMATIC	A, E, H	
3871	PINE OIL PUMILIO	A, E, H	
3872	PINEAPPLE	E	
3873	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%.
3874	PINELLIA TERNATA	A, H	
3875	PINUS CONTORTA	A, E, H	
3876	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%.
3877	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%.
3878	PINUS MONTICOLA	A, E, H	
3879	PINUS MUGO	A, E, H	
3880	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%.
3881	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%.
3882	PINUS PONDEROSA	A, E, H	
3883	PINUS RADIATA	A, E, H	

3884	PINUS STROBUS	A, E, H	
3885	PINUS SYLVESTRIS	A, E, H	
3886	PINUS TABULIFORMIS	A, E, H	
3887	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%.
3888	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%.
3889	PIPER CHABA	A, E, H	
3890	PIPER CUBEBA	A, E, H	
3891	PIPER KADSURA	A, E, H	
3892	PIPER LONGUM	A, E, H	
3893	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.
3894	PIPER NIGRUM	A, E, H	
3895	PIPER SARMENTOSUM	A, E, H	
3896	PIPERIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3897	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%.
3898	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%.

3899	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%.
3900	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%.
3901	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (PIPBUT) 'Contains piperonyl butoxide' (or words to that effect).
3902	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.
3903	PISCIDIA PISCIPULA	A, E, H	
3904	PISTACIA LENTISCUS	A, E, H	
3905	PISUM SATIVUM	A, E, H	
3906	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3907	PLANTAGO AFRA	A, E, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3908	PLANTAGO ARENARIA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).

3909	PLANTAGO ASIATICA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3910	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 medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3911	PLANTAGO MAJOR	A, E, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3912	PLANTAGO OVATA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement

			on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3913	PLANTAGO SEED DRY	A, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3914	PLATANUS OCCIDENTALIS	A, E, H	
3915	PLATANUS RACEMOSA	A, H	
3916	PLATANUS X ACERIFOLIA	A, H	
3917	PLATYCODON GRANDIFLORUS	A, E, H	
3918	PLECTRANTHUS BARBATUS	A, E, H	
3919	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%.
3920	PLUM	E	
3921	PLUMBAGO EUROPAEA	A, H	
3922	PLUMERIA ALBA	A, E, H	
3923	PLUMERIA RUBRA	A, E, H	

3924	POA NEMORALIS	A, H	
3925	POA PRATENSIS	A, H	
3926	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%.
3927	POGOSTEMON CABLIN	A, E, H	
3928	POLACRILIN	E	
3929	POLACRILIN POTASSIUM	E	
3930	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).
3931	POLIGLUSAM	A, E	When for internal use, the following warning statements are required on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect); and - (SFOOD) 'Derived from seafood'. When for internal use and the dosage form is a powdered preparation, the medicine requires the following warning statements on the medicine label: - (DNTPOW) 'Do not take powder alone. Mix with food or fluid'. When used as an excipient, only for use in topical medicines for dermal application. In addition, when the ingredient is included in a medicine that is listed in the

			Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a) & (b). a) The average molecular mass of poliglusam must be greater than 2 kilodaltons. b) When for internal use, the medicine must not contain more than 1750 milligrams of poliglusam per maximum recommended daily dose.
3932	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	When for oral use, the medicine must provide no more than 2000 milligrams of Poliglusam derived from Aspergillus niger per maximum recommended daily dose and requires the following warning statement on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect). If the medicine is a powdered dosage form, the medicine also requires the following warning

			statement on the medicine label: - 'Do not take powder alone. Mix with food or fluid.' When used as an excipient, Poliglusam derived from Aspergillus niger is only permitted for use in topical medicines for dermal application.
3933	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.
3934	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).
3935	POLOXAMER	E	Only for use in topical medicines for dermal application.
3936	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%.
3937	POLOXAMINE 1301	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3938	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%.
3939	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%.
3940	POLYACRYLATE CROSSPOLYMER-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

			for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3941	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%.
3942	POLYACRYLIC ACID	E	
3943	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3944	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%.
3945	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3946	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%.
3947	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%.
3948	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%.
3949	POLYDEXTROSE	E	
3950	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%.

3951	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%
3952	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%.
3953	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%.
3954	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%.

3955	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%.
3956	POLYETHYLENE	E	
3957	POLYGALA CHINENSIS	A, H	
3958	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.
3959	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
3960	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
3961	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%.

3962	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%.
3963	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%.
3964	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3965	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%.
3966	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3967	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%.
3968	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
3969	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%.
3970	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%.
3971	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%.
3972	POLYGLYCERYL-3 POLYRICINOLEATE	E	
3973	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%.
3974	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%.
3975	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%.
3976	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
3977	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%.
3978	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
3979	POLYGONATUM MULTIFLORUM	A, H	
3980	POLYGONATUM OFFICINALE	A, H	
3981	POLYGONATUM SIBIRICUM	A, E, H	
3982	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%.
3983	POLYGONUM BISTORTA	A, H	
3984	POLYGONUM ODORATUM	A, H	
3985	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
3986	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.
3987	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
3988	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%.

3989	POLYMETHACRYLIC ACID	E	
3990	POLYMETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
3991	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%.
3992	POLYPORUS UMBELLATUS	A, H	
3993	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
3994	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%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than

			1%.
3995	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
3996	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
3997	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%.
3998	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
3999	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
4000	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%.

4001	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%.
4002	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%.
4003	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%.
4004	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
4005	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%
4006	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%.
4007	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 be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1

			January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4008	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%.
4009	POLYSORBATE 20	E	
4010	POLYSORBATE 40	E	
4011	POLYSORBATE 60	E	
4012	POLYSORBATE 65	E	
4013	POLYSORBATE 80	E	
4014	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4015	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%.
4016	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.
4017	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%.
4018	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4019	POLYVINYL ACETATE PHTHALATE	E	
4020	POLYVINYL ALCOHOL	E	
4021	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal

			application.
4022	POMEGRANATE	E	
4023	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4024	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.
4025	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%.
4026	POPPY SEED	E, H	
4027	POPPY SEED OIL	E, H	
4028	POPULUS ALBA	A, H	
4029	POPULUS BALSAMIIFERA	A, E, H	
4030	POPULUS CANDICANS	A, H	
4031	POPULUS DELTOIDES	A, H	
4032	POPULUS NIGRA	A, H	

4033	POPULUS TREMULA	A, H	
4034	POPULUS TREMULOIDES	A, H	
4035	PORCINE	H	Only for use as an active homoeopathic ingredient.
4036	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%.
4037	PORTULACA OLERACEA	A, E, H	
4038	POTABLE WATER	E	
4039	POTASSIUM ACETATE	E	
4040	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4041	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4042	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.

4043	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4044	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.
4045	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.
4046	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.
4047	POTASSIUM BICARBONATE	E	

4048	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4049	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.
4050	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4051	POTASSIUM CHLORIDE	A, E, H	When for oral use: a) potassium is a mandatory component of potassium chloride; b) the medicine requires the following warning statement on the medicine label: - (POTAS) 'Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and c) other than when used for oral rehydration therapy, the concentration must be no more than 550 mg per dosage unit. Medicines for use as oral rehydration therapy, are subject

			to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and c) the medicine requires the warning statements: - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration in the medicine must be no more than 3.75%.
4052	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.

4053	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%.
4054	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%.
4055	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4056	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.
4057	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.

4058	POTASSIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4059	POTASSIUM HYDROXYCITRATE	A, H	
4060	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.
4061	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 contains less than 300 micrograms of iodine. When for external use, the concentration of iodine in the medicine (excluding salts derivatives or iodophors) must not exceed 2.5%.
4062	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%.
4063	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%.
4064	POTASSIUM NITRATE	A, H	Only for dental use.

			The concentration in the medicine must be no more than 5%.
4065	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.
4066	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%.
4067	POTASSIUM SORBATE	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains

			[insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4068	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%.
4069	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4070	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.
4071	POTATO STARCH	E	
4072	POTENTILLA ANSERINA	A, H	
4073	POTENTILLA CHINENSIS	A, H	

4074	POTENTILLA DISCOLOR	A, H	
4075	POTENTILLA ERECTA	A, E, H	
4076	POTENTILLA REPTANS	A, H	
4077	POTERIUM OFFICINALE	A, E, H	
4078	POTERIUM SANGUISORBA	A, H	
4079	POVIDONE	E	
4080	POWDERED CELLULOSE	E	
4081	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%.
4082	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%.
4083	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%.

4084	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%.
4085	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%.
4086	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4087	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%.
4088	PPG-20 LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal

	ETHER		application.
4089	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%.
4090	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4091	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%.
4092	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4093	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4094	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal

			application.
4095	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%.
4096	PREGELATINISED MAIZE STARCH	E	
4097	PREGELATINISED POTATO STARCH	E	
4098	PREGELATINISED RICE STARCH	E	
4099	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4100	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%.
4101	PRICKLY ASH BARK DRY	A, H	
4102	PRICKLY ASH BARK POWDER	A, H	
4103	PRIMULA VERIS	A, E, H	
4104	PRIMULA VULGARIS	A, E, H	
4105	PRINSEPIA UNIFLORA	A, H	
4106	PROBOSCIDEA PARVIFLORA	A, H	
4107	PROGESTERONE	H	Only for use as an active homoeopathic ingredient.
4108	PROLINE	A, E	
4109	PROPAN-1-OL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 18%.
4110	PROPANE	E	Only for use as an excipient propellant ingredient.
4111	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%.
4112	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%.
4113	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%.
4114	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%.
4115	PROPIONYLLEVOCARNITINE HYDROCHLORIDE	A, H	
4116	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 irritation or swelling of the mouth or throat occurs, discontinue use.'
4117	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.'
4118	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.'

4119	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.'
4120	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.'
4121	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.'
4122	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%.
4123	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%.
4124	PROPYL GALLATE	E	
4125	PROPYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4126	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.

4127	PROPYLENE GLYCOL	E	
4128	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%.
4129	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%.
4130	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%.
4131	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4132	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.

4133	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4134	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%.
4135	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4136	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4137	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4138	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4139	PROSOPIS JULIFLORA	A, H	
4140	PROTEASE	A	Must be derived from Aspergillus oryzae or Aspergillus niger. When the dosage form is

			undivided, the units 'haemoglobin unit on the tyrosine basis per gram' and 'Thousand haemoglobin units on the tyrosine basis per gram' are permitted. When the dosage form is divided, the units 'haemoglobin units on the tyrosine basis' and 'thousand haemoglobin units on the tyrosine basis' are permitted.
4141	PROTEIN HYDROLYSATE	E	
4142	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%.
4143	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%.
4144	PRUNELLA VULGARIS	A, H	
4145	PRUNUS AFRICANA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus africana. The concentration of Amygdalin in the medicine

			must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4146	PRUNUS ARMENIACA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus armeniaca and must be declared in the application. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4147	PRUNUS AVIUM	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus avium. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4148	PRUNUS CERASIFERA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus

			cerasifera. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4149	PRUNUS CERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasus. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4150	PRUNUS DOMESTICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4151	PRUNUS DULCIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus dulcis

			when the plant part is seed. When the plant part is seed, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry seed. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4152	PRUNUS HUMILIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus humilis. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4153	PRUNUS JAPONICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus japonica. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than

			1 microgram/kg or 1 microgram/L or 0.0000001%.
4154	PRUNUS LAUROCERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4155	PRUNUS MUME	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus mume. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4156	PRUNUS PERSICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus persica. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1

			microgram/L or 0.0000001%.
4157	PRUNUS SALICINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4158	PRUNUS SEROTINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus serotina. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4159	PRUNUS SPINOSA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1

			microgram/L or 0.0000001%.
4160	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4161	PSEUDOCYDONIA SINENSIS	A, H	
4162	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4163	PSEUDOTSUGA MENZIESII	A, H	
4164	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4165	PSIDIUM GUAJAVA	A, E, H	
4166	PSORALEN (OF CULLEN CORYLIFOLIUM)	E	
4167	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4168	PSYLLIUM HUSK DRY	A, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4169	PSYLLIUM HUSK POWDER	A, E, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).

4170	PSYLLIUM SEED DRY	A, E, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4171	PTELEA TRIFOLIATA	A, H	
4172	PTEROCARPUS MARSUPIUM	A, H	
4173	PTEROCARPUS SANTALINUS	A, E, H	
4174	PUERARIA LOBATA	A, E, H	
4175	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4176	PULLULAN	E	
4177	PUMICE	E	
4178	PUMPKIN	E	
4179	PUMPKIN SEED	E, H	
4180	PUMPKIN SEED OIL	E, H	
4181	PUNICA GRANATUM	A, E, H	
4182	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4183	PURIFIED HONEY	A, E	When the route of administration is oral, the medicine requires the following warning statement on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve

			months' (or words to that effect). When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
4184	PURIFIED SILICEOUS EARTH	E, H	
4185	PURIFIED TALC	E	
4186	PURIFIED WATER	E	
4187	PVM/MA COPOLYMER	E	
4188	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4189	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal

			application.
4190	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4191	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).
4192	PYRIDOXAL 5-PHOSPHATE	A, E	Pyridoxine is a mandatory component of Pyridoxal 5-phosphate. The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the

			following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
4193	PYRIDOXAL 5-PHOSPHATE MONOHYDRATE	A	Pyridoxine is a mandatory component of Pyridoxal 5-phosphate monohydrate. The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
4194	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 must provide no more than 200 mg of pyridoxine. If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
4195	PYROGLUTAMIC ACID	E	
4196	PYROLA DECORATA	A, H	
4197	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%.

4198	PYRROSIA LINGUA	A, H	
4199	PYRROSIA PETIOLOSA	A, H	
4200	PYRROSIA SHEARERI	A, H	
4201	PYRUS COMMUNIS	A, E, H	Arbutin is a mandatory component of Pyrus communis. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
4202	PYRUS PYRIFOLIA	A, H	Arbutin is a mandatory component of Pyrus pyrifolia. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
4203	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%.
4204	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%.
4205	QUASSIA AMARA	A, E, H	
4206	QUASSIA WOOD JAMAICAN DRY	A, H	
4207	QUASSIA WOOD JAMAICAN POWDER	A, H	
4208	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4209	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4210	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4211	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.
4212	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%.
4213	QUERCETIN	A	
4214	QUERCETIN DIHYDRATE	A	
4215	QUERCUS ACUTISSIMA	A, H	
4216	QUERCUS ALBA	A, E, H	
4217	QUERCUS PALUSTRIS	A, H	
4218	QUERCUS ROBUR	A, H	
4219	QUERCUS RUBRA	A, H	
4220	QUERCUS VIRGINIANA	A, H	
4221	QUILLAIA DRY	A, H	
4222	QUILLAIA POWDER	A, E, H	
4223	QUILLAJA SAPONARIA	A, H	
4224	QUINCE	E	
4225	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.
4226	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.
4227	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4228	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4229	QUISQUALIS INDICA	A, H	
4230	R-ALPHA LIPOIC ACID	A	
4231	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%.
4232	RACEMIC CAMPHOR	E, H	Only for use as an active homoeopathic or excipient ingredient. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted 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.
4233	RADISH	E	
4234	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%.
4235	RANUNCULUS BULBOSUS	A, H	

4236	RANUNCULUS FICARIA	A, H	
4237	RANUNCULUS TERNATUS	A, H	
4238	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%.
4239	RAPHANUS SATIVUS	A, H	
4240	RASPBERRY	E	
4241	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%.
4242	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%.
4243	RASPBERRY ESSENCE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4244	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%.
4245	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%.
4246	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%.
4247	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%.
4248	RED 27	E	Permitted for use only as a colour for oral and topical use. The concentration in the medicine must be no more than

			0.5%.
4249	RED 27 ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use. The concentration in the medicine must be no more than 0.5%.
4250	RED ANT	H	Only for use as an active homoeopathic ingredient.
4251	RED CLOVER FLOWER DRY	A, H	
4252	RED CLOVER FLOWER POWDER	A, H	
4253	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4254	RED DEER	A	
4255	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4256	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4257	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4258	REHMANNIA GLUTINOSA	A, E, H	
4259	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%.
4260	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%.
4261	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%.
4262	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'.
4263	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.'
4264	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.'
4265	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.'
4266	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4267	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%.
4268	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'.
4269	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'.
4270	RHATANY ROOT DRY	A, H	
4271	RHATANY ROOT POWDER	A, H	
4272	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'.
4273	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'.
4274	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'.
4275	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'.
4276	RHODAMINE B	E	Permitted for use only as a colour for topical use.

4277	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%.
4278	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%.
4279	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.
4280	RHODODENDRON AUREUM	A, H	
4281	RHODODENDRON FERRUGINEUM	A, H	Arbutin is a mandatory component of Rhododendron ferrugineum. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the

			hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
4282	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4283	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'.
4284	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'.
4285	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'.
4286	RHUS AROMATICA	A, E, H	
4287	RHUS CHINENSIS	A, H	
4288	RHUS GLABRA	A, E, H	
4289	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4290	RIBES GROSSULARIA	A, E, H	
4291	RIBES NIGRUM	A, E, H	
4292	RIBOFLAVIN	A, E	
4293	RIBOFLAVIN SODIUM PHOSPHATE	A, E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’
4294	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.

4295	RIBOFLAVINE	A, E	
4296	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4297	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4298	RIBOSE	A	Only for use in oral medicines. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4299	RICE	E	

4300	RICE BRAN	E	
4301	RICE BRAN OIL	E	
4302	RICE BRAN WAX	A, E, H	
4303	RICE STARCH	E	
4304	RICE VINEGAR	E	
4305	RICE WINE	E	Ethanol is a mandatory component of Rice wine. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
4306	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4307	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4308	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.
4309	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of

			the dry herbal material.
4310	ROSA ARVENSIS	A, E, H	
4311	ROSA CANINA	A, E, H	
4312	ROSA CYMOSA	A, E, H	
4313	ROSA EGLANTERIA	A, E, H	
4314	ROSA GALLICA	A, E, H	
4315	ROSA LAEVIGATA	A, E, H	
4316	ROSA MULTIFLORA	A, E, H	
4317	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%.
4318	ROSA RUGOSA	A, E, H	
4319	ROSA VILLOSA	A, E, H	
4320	ROSA X CENTIFOLIA	A, E, H	
4321	ROSA X DAMASCENA	A, E, H	
4322	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%.

4323	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%.
4324	ROSE FRUIT FRESH	A, E, H	
4325	ROSE HIP	E	
4326	ROSE OIL	A, E, H	
4327	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%.
4328	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%.
4329	ROSMARINUS OFFICINALIS	A, E, H	Camphor and cineole are mandatory components of Rosmarinus officinalis. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations other

			than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
4330	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'.
4331	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'.
4332	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'.

4333	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4334	RUBIA CORDIFOLIA	A, H	
4335	RUBIA TINCTORUM	A, H	
4336	RUBUS CHINGII	A, H	
4337	RUBUS CORCHORIFOLIUS	A, H	
4338	RUBUS COREANUS	A, E, H	
4339	RUBUS FRUTICOSUS	A, E, H	
4340	RUBUS IDAEUS	A, E, H	
4341	RUBUS OCCIDENTALIS	A, E, H	
4342	RUBUS PARVIFOLIUS	A, H	
4343	RUBUS ROSIFOLIUS	A, H	
4344	RUDBECKIA HIRTA	A, H	
4345	RUE OIL	A, H	
4346	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%.
4347	RUMEX ACETOSA	A, H	
4348	RUMEX ACETOSELLA	A, H	
4349	RUMEX CONGLOMERATUS	A, H	

4350	RUMEX CRISPUS	A, E, H	
4351	RUMEX PULCHER	A, H	
4352	RUMEX SCUTATUS	A, H	
4353	RUSCUS ACULEATUS	A, H	
4354	RUTA GRAVEOLENS	A, E, H	
4355	RUTOSIDE	A, E	
4356	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4357	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).

4358	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%.
4359	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%.
4360	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%.
4361	SACCHARIN	E	The medicine requires the following warning statement on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect).
4362	SACCHARIN SODIUM	E	The medicine requires the following warning statement on the medicine label:

			- (SACCH) 'Contains saccharin' (or words to that effect). When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4363	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4364	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4365	SACCHAROMYCES CERVISIAE 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%.
4366	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.

4367	SACCHARUM OFFICINARUM	A, E, H	
4368	SAFFLOWER OIL	A, E, H	
4369	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4370	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%.
4371	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%.
4372	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'
4373	SAGE OIL SPANISH	A, E, H	
4374	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%.
4375	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%.
4376	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.

4377	SALIX ALBA	A, E, H	
4378	SALIX DAPHNOIDES	A, H	
4379	SALIX DISCOLOR	A, H	
4380	SALIX FRAGILIS	A, H	
4381	SALIX NIGRA	A, H	
4382	SALIX PURPUREA	A, H	
4383	SALSOLA KALI	A, H	
4384	SALVIA CHINENSIS	A, H	
4385	SALVIA FRUTICOSA	A, H	
4386	SALVIA HISPANICA	A, E, H	
4387	SALVIA LAVANDULAEFOLIA	A, H	
4388	SALVIA MILTIORRHIZA	A, H	
4389	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%.
4390	SALVIA SCLAREA	A, E, H	
4391	SAMBUCUS CANADENSIS	A, H	
4392	SAMBUCUS EBULUS	A, H	
4393	SAMBUCUS NIGRA	A, E, H	
4394	SANDALWOOD OIL EAST INDIAN	A, E, H	
4395	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than

			4X.
4396	SANICULA EUROPAEA	A, H	
4397	SANTALUM ALBUM	A, E, H	
4398	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.
4399	SAPINDUS MUKOROSSI	A, H	
4400	SAPONARIA OFFICINALIS	A, H	
4401	SAPOSHNIKOVIA DIVARICATA	A, H	
4402	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%.
4403	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.
4404	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.
4405	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%.
4406	SATUREIA HORTENSIS	A, H	
4407	SATUREIA MONTANA	A, H	

4408	SAUROPUS SPATULIFOLIUS	A, H	
4409	SAURURUS CHINENSIS	A, H	
4410	SAUSSUREA COSTUS	A, H	
4411	SAVORY OIL SUMMER	A, H	
4412	SAXIFRAGA GRANULATA	A, E, H	
4413	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%.
4414	SCAPHIUM SCAPHIGERUM	A, H	
4415	SCHEFFLERA HEPTAPHYLLA	A, H	
4416	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4417	SCHINUS MOLLE	A, H	
4418	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%.
4419	SCHISANDRA CHINENSIS	A, E, H	
4420	SCHIZONEPETA TENUIFOLIA	A, E, H	
4421	SCHOENOCAULON OFFICINALE	A, H	The maximum recommended daily dose must contain no

			more than the equivalent of 1mg of the dry herbal material.
4422	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%.
4423	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%.
4424	SCLERANTHUS ANNUUS	A, H	
4425	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4426	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%.
4427	SCROPHULARIA NINGPOENSIS	A, H	
4428	SCROPHULARIA NODOSA	A, H	
4429	SCURRULA PARASITICA VAR.	A, H	

	GRACILIFLORA		
4430	SCUTELLARIA BAICALENSIS	A, E, H	
4431	SCUTELLARIA BARBATA	A, H	
4432	SCUTELLARIA LATERIFLORA	A, E, H	
4433	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%.
4434	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%.
4435	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%.
4436	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. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4437	SEDUM ACRE	A, H	
4438	SELAGINELLA TAMARISCINA	A, H	
4439	SELENICEREUS GRANDIFLORUS	A, E, H	
4440	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.'
4441	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.'
4442	SELENOMETHIONINE	A	Selenium is a mandatory component of Selenomethionine for oral and sublingual use. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micograms for adults of selenium from dietary supplements should not be exceeded.'

4443	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4444	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.
4445	SEMOLINA	E	
4446	SEMPERVIVUM TECTORUM	A, H	
4447	SENEGA ROOT DRY	A, H	
4448	SENEGA ROOT POWDER	A, H	
4449	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'.

4450	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'.
4451	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'.
4452	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'.
4453	SENNA FRUIT TINNEVELLY	A, H	When for oral or sublingual, Hydroxyanthracene glycosides

	POWDER	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'.
4454	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'.
4455	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'.
4456	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'.
4457	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'.
4458	SEPIA	H	Only for use as an active homoeopathic ingredient.
4459	SEQUOIA SEMPERVIRENS	A, H	
4460	SEQUOIADENDRON GIGANTEUM	A, H	
4461	SERENOA REPENS	A, H	
4462	SERINE	A, E	
4463	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4464	SESAME OIL	A, E, H	
4465	SESAME SEED	E	
4466	SESAMUM INDICUM	A, E, H	
4467	SETARIA ITALICA	A, H	
4468	SHARK CALCIUM CHONDROITIN SULFATE	A	
4469	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)

4470	SHARK CHONDROITIN SULFATE	A	
4471	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4472	SHARK SODIUM CHONDROITIN SULFATE	A	
4473	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.'
4474	SHEA BUTTER	E	
4475	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4476	SHELLAC	E	
4477	SHEPHERD'S PURSE HERB DRY	A, H	
4478	SHEPHERD'S PURSE HERB POWDER	A, H	
4479	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%.

4480	SIGESBECKIA ORIENTALIS	A, E, H	
4481	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%.
4482	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%.
4483	SILICA SILYLATE	E	Only for use in topical medicines for dermal application.
4484	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4485	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4486	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).
4487	SILVER	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 1%.
4488	SILVER BEET	E, H	
4489	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%.
4490	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.

4491	SILYBUM MARIANUM	A, E, H	
4492	SIMABA CEDRON	A, H	
4493	SIMETHICONE	E	
4494	SIMMONDSIA CHINENSIS	A, E, H	
4495	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%.
4496	SINAPIS ARVENSIS	A, H	
4497	SINOMENIUM ACUTUM	A, H	
4498	SIPHONESTEGIA CHINENSIS	A, H	
4499	SIRAITIA GROSVENORII	A, E, H	
4500	SISYMBRIUM OFFICINALE	A, H	
4501	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%.
4502	SKIPJACK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of

	Shark-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per 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.'
4503	SLIPPERY ELM BARK DRY	A, H	
4504	SLIPPERY ELM BARK POWDER	A, E, H	
4505	SMILAX ARISTOLOCHIIFOLIA	A, H	
4506	SMILAX CHINA	A, H	
4507	SMILAX GLABRA	A, H	
4508	SMILAX OFFICINALIS	A, E, H	
4509	SMILAX ORNATA	A, E, H	
4510	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%.
4511	SODIUM ACETATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'

4512	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%.
4513	SODIUM ACID CITRATE	A, E, H	When used as an active ingredient, only for use in oral medicines. When used as an active, only for use in oral medicines. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4514	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%.

4515	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).
4516	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).
4517	SODIUM ALGINATE	E	
4518	SODIUM ASCORBATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4519	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%.
4520	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%.
4521	SODIUM BENZOATE	E	Medicines containing benzoates require the following warning statement on the medicine label: - (TBNZO8) ‘Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or ‘Contains [insert the approved name of benzoate used]’ (or words to this effect) if product contains one benzoate source. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine

			label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4522	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4523	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4524	SODIUM BICARBONATE	A, E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' When used as an active ingredient, the medicine may only be for oral rehydration

	salts in powdered and effervescent tablet dosage forms. Medicines for use as oral rehydration therapy are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.' c) the medicine requires the following warning statements on the medicine label: - (UOAD) 'Use only as directed.' - (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice (or words to that effect).' - (DIAR3) 'If diarrhoea

			persists, seek medical advice.'
4525	SODIUM BISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4526	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4527	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4528	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.

4529	SODIUM CARBONATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4530	SODIUM CARBONATE MONOHYDRATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4531	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%.

4532	SODIUM CARRAGEENAN	E	
4533	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%.
4534	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4535	SODIUM CHLORIDE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). 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.

4536	SODIUM CHONDROITIN SULFATE	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%.
4537	SODIUM CITRATE	A, E	Only for oral use when used as an active ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4538	SODIUM CITRATE DIHYDRATE	A, E	Only for oral use when used as an active ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of

			this medicine contains [state quantity and units] of sodium' (or words to that effect).
4539	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%.
4540	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4541	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4542	SODIUM CYCLAMATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4543	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal

			application.
4544	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%.
4545	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4546	SODIUM ERYTHORBATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4547	SODIUM ETHYL HYDROXYBENZOATE	E	
4548	SODIUM FLUORIDE	A, E, H	Fluoride is a mandatory

		component of Sodium fluoride. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When used as an active ingredient, it is subject to the following conditions: a) Only for use in combination with at least one other listable therapeutically active ingredient. b) The concentration of fluoride ion must be no more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.' When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'

4549	SODIUM FUMARATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4550	SODIUM GLYCEROPHOSPHATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4551	SODIUM HYALURONATE	E	Only for use in topical medicines for dermal application.
4552	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4553	SODIUM HYDROXIDE	E	The concentration in the medicine must be no more than

			5%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4554	SODIUM HYDROXYCITRATE	A	
4555	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%.
4556	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.

4557	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of Sodium hypochlorite. The concentration of chlorine in the medicine must be no more than 4%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4558	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4559	SODIUM LACTATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).

4560	SODIUM LAURETH SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4561	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%.
4562	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%.
4563	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4564	SODIUM LAURYL PHOSPHATE	E	When for oral or sublingual use and the total amount of sodium

			from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4565	SODIUM LAURYL SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4566	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4567	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4568	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%.
4569	SODIUM METABISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4570	SODIUM METAPHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must not be more than 0.1%.

4571	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine must be no more than 2%.
4572	SODIUM METHYL HYDROXYBENZOATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4573	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.
4574	SODIUM MONOFLUOROPHOSPHATE	A	Fluoride is a mandatory component of sodium monofluorophosphate. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When used as an active ingredient, it is subject to the following conditions: a) Only for use in combination with at least one other listable therapeutically active ingredient. b) The concentration of fluoride ion must be no more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or

			less.' When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4575	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%.
4576	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4577	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4578	SODIUM PANTOTHENATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning

			statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4579	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4580	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 preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron from all ingredients in the product must not exceed 3500 mg/kg or 3500 mg/L or 0.35%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'

4581	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.
4582	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4583	SODIUM POLYACRYLATE STARCH	E	Only to be used in a medicine where Procter & Gamble Australia Pty Ltd (Client ID 11364), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 27 September 2020. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 1%.
4584	SODIUM POLYMETAPHOSPHATE	E	

4585	SODIUM PROPIONATE	E	Only for use in topical medicines for dermal application.
4586	SODIUM PROPYL HYDROXYBENZOATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4587	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%.

4588	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.'
4589	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.'
4590	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.'
4591	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.'
4592	SODIUM SILICATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4593	SODIUM STARCH GLYCOLLATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium'

			(or words to that effect).
4594	SODIUM STARCH GLYCOLLATE TYPE A	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4595	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4596	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%.
4597	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%.

4598	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4599	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%.
4600	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4601	SODIUM SULFATE	A, E, H	When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label: - (LAX4) 'Substance may have a laxative effect'. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium'

			(or words to that effect).
4602	SODIUM SULFATE DECAHYDRATE	A, E, H	When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label: - (LAX4) 'Substance may have a laxative effect'. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4603	SODIUM SULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label:

			- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4604	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application. Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4605	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%.

4606	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.
4607	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.
4608	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%.
4609	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.
4610	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.
4611	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.
4612	SOLIDAGO GIGANTEA	A, H	
4613	SOLIDAGO GIGANTEA MIS	A, E, H	
4614	SOLIDAGO VIRGAUREA	A, E, H	
4615	SOLUBLE MAIZE STARCH	E	
4616	SOLUBLE POTATO STARCH	E	
4617	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4618	SOLVENT RED 1	E	Permitted for use only as a

			colour for topical use.
4619	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4620	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%.
4621	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4622	SOPHORA FLAVESCENS	A, E, H	
4623	SOPHORA TONKINENSIS	A, H	
4624	SORBIC ACID	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4625	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4626	SORBITAN MONO-OLEATE	E	

4627	SORBITAN MONOLAURATE	E	
4628	SORBITAN MONOSTEARATE	E	
4629	SORBITAN OLEATE	E	
4630	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%.
4631	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%.
4632	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4633	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4634	SORBITAN STEARATE	E	
4635	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.

4636	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.
4637	SORBITOL SOLUTION (70 PER CENT) (CRYSTALLISING)	A, E	Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (crystallising). When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) ‘Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).'

4638	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. When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).'
4639	SORBUS AUCUPARIA	A, H	
4640	SORBUS DOMESTICA	A, H	
4641	SORGHUM	E	
4642	SORGHUM VULGARE	A, H	
4643	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched

	LIQUID		soy lecithin liquid. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4644	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4645	SOY POLYSACCHARIDE	E	
4646	SOY PROTEIN	E	
4647	SOY STEROL	E	
4648	SOYA BEAN	E	
4649	SOYA BRAN	E	
4650	SOYA OIL	A, E, H	
4651	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%.
4652	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%.
4653	SPARGANIUM STOLONIFERUM	A, H	
4654	SPARTIUM JUNCEUM	A, H	
4655	SPATHOLOBUS SUBERECTUS	A, H	
4656	SPEARMINT OIL	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of spearmint oil. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) 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; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4657	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: a) the medicine must not be intended for use in the eye or on damaged skin; b) the maximum concentration of menthol must not exceed 5%; and c) the medicine requires the

			following warning statements 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; and - (EYE) Avoid contact with eyes (or words to that effect). When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4658	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%.
4659	SPIGELIA ANTHELMIA	A, H	
4660	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4661	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.
4662	SPINACH	E	
4663	SPINACIA OLERACEA	A, E, H	
4664	SPIRODELA POLYRRHIZA	A, H	
4665	SPIRULINA	E	
4666	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4667	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4668	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%.
4669	SQUALANE	E	Only for use in topical medicines for dermal application.
4670	SQUALENE	A, E	
4671	SQUID OIL	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'. Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in combination with other ingredients in the medicine and be presented in a therapeutic dosage form for therapeutic use.
4672	SQUILL DRY	A, H	
4673	SQUILL INDIAN DRY	A, H	

4674	SQUILL INDIAN POWDER	A, H	
4675	SQUILL POWDER	A, H	
4676	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.'
4677	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.'
4678	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.'
4679	STACHYS OFFICINALIS	A, E, H	
4680	STACHYS PALUSTRIS	A, H	

4681	STACHYURUS HIMALAICUS	A, H	
4682	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%.
4683	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4684	STAR ANISE OIL	A, E	When the concentration in the medicine is more than 50% and the nominal capacity of the container is equal to or less than 50mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4685	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%.
4686	STARCH SODIUM OCTENYL	E	

	SUCCINATE		
4687	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4688	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4689	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4690	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4691	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4692	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).

4693	STEARETH-10	E	Only for use in topical medicines for dermal application.
4694	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%.
4695	STEARETH-2	E	Only for use in topical medicines for dermal application.
4696	STEARETH-20	E	Only for use in topical medicines for dermal application.
4697	STEARETH-21	E	Only for use in topical medicines for dermal application.
4698	STEARETH-5	E	Only for use in topical medicines for dermal application.
4699	STEARIC ACID	E	
4700	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%.
4701	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%.
4702	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4703	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4704	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4705	STEARYL ALCOHOL	E	
4706	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).
4707	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4708	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4709	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%.
4710	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4711	STELLARIA CHAMAEJASME	A, H	
4712	STELLARIA DICHOTOMA	A, H	
4713	STELLARIA MEDIA	A, E, H	

4714	STEMONA JAPONICA	A, H	
4715	STEMONA SESSILIFOLIA	A, H	
4716	STENOTAPHRUM SECUNDATUM	A, H	
4717	STEPHANIA TETRANDA	A, H	
4718	STERCULIA	A, H	
4719	STERCULIA TRAGACANTHA	A, H	
4720	STERCULIA URENS	A, H	
4721	STEVIA REBAUDIANA	A, E, H	
4722	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4723	STILLINGIA SYLVATICA	A, H	
4724	STORAX PREPARED	A, E, H	
4725	STRAWBERRY	E	
4726	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%.
4727	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'.
4728	STREPTOCOCCUS THERMOPHILUS	A	
4729	STROBILANTHES CUSIA	A, H	
4730	STRONG AMMONIA SOLUTION	E	Ammonia is a mandatory component of dilute ammonia solution. The concentration of ammonia in the medicine must be no more than 0.5%. When for internal use, the concentration in the medicine must be no more than 0.25%.
4731	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4732	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4733	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4734	STRYCHNOS IGNATII	H	Only for use as an active homoeopathic ingredient.

			Strychnine (of Strychnos spp.) is a mandatory component of Strychnos ignatii. The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4735	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 be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4736	STYPHNOLOBIUM JAPONICUM	A, E, H	
4737	STYRAX BENZOIN	A, E, H	
4738	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%.
4739	STYRAX PARALLELONEURUM	A, H	
4740	STYRAX TONKINENSIS	A, H	

4741	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%.
4742	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4743	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%.
4744	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4745	SUCCINIC ACID	E	
4746	SUCRALOSE	E	
4747	SUCROSE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement

			on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4748	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%.
4749	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%.
4750	SUCROSE COCOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

			for use in the eye. The concentration in the medicine must be no more than 2%.
4751	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4752	SUCROSE LAURATE	E	When for oral or sublingual use, Sucrose is a mandatory component of Sucrose laurate. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4753	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory

			component of sucrose octaacetate. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
4754	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4755	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).
4756	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.
4757	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%.
4758	SUDAN III	E	Permitted for use only as a colour for topical use.

4759	SUGAR CANE WAX ALCOHOLS	A, H	The maximum recommended daily dose must not provide more than 12mg. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
4760	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of Sugarcane. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or

			words to that effect).
4761	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4762	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%.
4763	SULFUR DIOXIDE	E	Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4764	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4765	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%.
4766	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%.
4767	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 be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following

			statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4768	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 be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July

			2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4769	SUNFLOWER OIL	A, E, H	
4770	SUNFLOWER SEED	E, H	
4771	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4772	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4773	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4774	SWEDE	E	
4775	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%.
4776	SWEET POTATO	E	
4777	SWERTIA CHIRATA	A, H	
4778	SWIETENIA MAHOGANI	A, H	
4779	SYAGRUS ROMANZOFFIANA	A, E, H	
4780	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%.
4781	SYMPLOCARPUS FOETIDUS	A, H	
4782	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4783	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.
4784	SYNTHETIC WAX	E	
4785	SYRINGA RETICULATA	A, H	

4786	SYRINGA VULGARIS	A, H	
4787	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%.
4788	SYZYGIUM CUMINI	A, H	
4789	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%.
4790	TABEBUIA SERRATIFOLIA	A, E, H	
4791	TAGETES ERECTA	A, H	
4792	TAGETES MINUTA	A, E, H	
4793	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%.
4794	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4795	TALLOW	E	Only for use in topical medicines for dermal application.

4796	TALLOW GLYCERIDES	E	
4797	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%.
4798	TAMARIX APHYLLA	A, H	
4799	TAMARIX CHINENSIS	A, H	
4800	TAMARIX GALLICA	A, H	
4801	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.
4802	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4803	TANACETUM PARTHENIUM	A, E, H	
4804	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%.
4805	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%.
4806	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.
4807	TANNIC ACID	E	
4808	TAPIOCA STARCH	E	
4809	TARAXACUM MONGOLICUM	A, E, H	
4810	TARAXACUM OFFICINALE	A, E, H	
4811	TARO	E	
4812	TARRAGON OIL	A, E, H	
4813	TARTARIC ACID	E	
4814	TARTRAZINE	E	Permitted for use only as a colour for oral and topical use. The medicine requires the following warning statement

			on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4815	TARTRAZINE ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4816	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%.
4817	TAURINE	A, E	
4818	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4819	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'.
4820	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4821	TERMINALIA CATAPPA	A, H	
4822	TERMINALIA CHEBULA	A, H	
4823	TERMINALIA FERDINANDIANA	A, E, H	Only for use when the plant part is fruit flesh, fruit flesh dry or the preparation is as an aqueous extract of the fruit flesh. When used as an excipient, the ingredient is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. When used as an excipient, the concentration in the medicine must be no more than 0.3%.
4824	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%.
4825	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%.
4826	TERPINEOL	E	
4827	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%.

4828	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%.
4829	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%.
4830	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%.
4831	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%.
4832	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4833	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%.
4834	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%.
4835	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%.
4836	TETRACLINIS ARTICULATA	A, E, H	
4837	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%.
4838	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.
4839	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%.
4840	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%.
4841	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%.
4842	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%.
4843	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%.
4844	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%.
4845	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%.
4846	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%.
4847	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%.
4848	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%.
4849	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4850	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%.
4851	TETRAPANAX PAPYRIFER	A, H	
4852	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4853	TETRASODIUM PYROPHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state

			quantity and units] of sodium' (or words to that effect).
4854	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4855	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4856	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4857	THAPSIA GARGANICA	A, H	
4858	THAUMATIN	E	
4859	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%.
4860	THEMEDA TRIANDRA	A, H	
4861	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma

			cacao. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
4862	THEOBROMA OIL	A, E, H	
4863	THIAMINE	A, E	
4864	THIAMINE HYDROCHLORIDE	A, E	
4865	THIAMINE NITRATE	A, E	
4866	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%.
4867	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%.
4868	THLASPI ARVENSE	A, E, H	
4869	THREONINE	A, E	
4870	THUJA OCCIDENTALIS	A, H	
4871	THUJA PLICATA	A, E, H	
4872	THYME HERB DRY	A, E, H	
4873	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).
4874	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 topical medicines for dermal applications.
4875	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).
4876	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4877	THYMUS MASTICHINA	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4878	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).
4879	THYMUS VULGARIS	A, E, H	When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4880	THYMUS VULGARIS MIS	A, E, H	When the plant preparation is an oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus vulgaris mis oil or distillate in the preparation is greated than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the

			medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4881	THYMUS ZYGIS	A, H	When the plant preparation is an oil or a distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus zygis oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4882	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4883	TILACTASE	A	Must be derived from Aspergillus oryzae and comply with the relevant USP monograph. When the dosage form is undivided, the units 'acid lactase units per gram' and 'Thousand acid lactase units per gram' are permitted. When the dosage form is divided, the units 'acid lactase

			units' and 'thousand acid lactase units' are permitted.
4884	TILIA CORDATA	A, E, H	
4885	TILIA PLATYPHYLLOS	A, E, H	
4886	TILIA TOMENTOSA	A, H	
4887	TILIA X VULGARIS	A, E, H	
4888	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%.
4889	TIN	H	Only for use as an active homoeopathic ingredient.
4890	TINOSPORA CORDIFOLIA	A, H	
4891	TINOSPORA SINENSIS	A, H	
4892	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 in oral medicines and as a colour in topical medicines for dermal application. Not to be included in medicines intended for use in the eye.

			When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4893	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%.
4894	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%
4895	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%.
4896	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%

4897	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4898	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%.
4899	TOLU BALSAM	A, E, H	
4900	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%.
4901	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%.

4902	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%.
4903	TOMATO	E	
4904	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%.
4905	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%.
4906	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%.
4907	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4908	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.
4909	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4910	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4911	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4912	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%.
4913	TRAGACANTH	A, E	
4914	TRAMETES VERSICOLOR	A, H	
4915	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4916	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%.
4917	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.
4918	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%.
4919	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%.
4920	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%.
4921	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%.
4922	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%.
4923	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%.
4924	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%.
4925	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%.
4926	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%.
4927	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%.

4928	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%.
4929	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%.
4930	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%.
4931	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%.
4932	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%.
4933	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%.
4934	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of Treacle. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning

			statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4935	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%.
4936	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.
4937	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.
4938	TREMELLA FUCIFORMIS	A, H	
4939	TRIACETIN	E	
4940	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4941	TRIADICA SEBIFERA	A, H	
4942	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.

4943	TRIBASIC SODIUM PHOSPHATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4944	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%.
4945	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%.
4946	TRIBULUS TERRESTRIS	A, E, H	
4947	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%.
4948	TRICALCIUM PHOSPHATE	E	
4949	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%.
4950	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%.
4951	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.

4952	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%.
4953	TRICHODERMA VIRIDE	A, E, H	
4954	TRICHOSANTHES KIRILOWII	A, E, H	
4955	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
4956	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%.
4957	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%.

4958	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4959	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%.
4960	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%.
4961	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
4962	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%.
4963	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%.
4964	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
4965	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
4966	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%.
4967	TRIETHYL CITRATE	E	
4968	TRIETHYLENE GLYCOL	E	
4969	TRIFOLIUM PRATENSE	A, E, H	
4970	TRIFOLIUM REPENS	A, H	

4971	TRIGONELLA FOENUM-GRAECUM	A, E, H	
4972	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%.
4973	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
4974	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
4975	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%.
4976	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%.
4977	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
4978	TRILAURIN	E	Only for use in topical medicines for dermal application.
4979	TRILISA ODORATISSIMA	A, H	
4980	TRILLIUM ERECTUM	A, H	
4981	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%.
4982	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%.
4983	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%.
4984	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%.
4985	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%.
4986	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%.
4987	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
4988	TRIMETHYLPENTANEDIOL/ADI	E	Only for use in topical

	PIC ACID/GLYCERIN CROSSPOLYMER		medicines for dermal 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%.
4989	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
4990	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient.
4991	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%.
4992	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%.
4993	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%.
4994	TRIOSTEUM PERFOLIATUM	A, H	
4995	TRIOXAUNDECANEDIOIC ACID	E	
4996	TRIPAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4997	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%.
4998	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 be no more than 10%. When used topically, the

			dosage form must not be spray. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4999	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%.

5000	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
5001	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%.
5002	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%.
5003	TRISTEARIN	E	
5004	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. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert

			name of ingredient]' (or words to that effect).
5005	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. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
5006	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%.
5007	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5008	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.

5009	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 be no more than 12%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

5010	TROLLIUS CHINENSIS	A, H	
5011	TROMETAMOL	E	
5012	TROMETAMOL HYDROCHLORIDE	E	
5013	TROPAEOLUM MAJUS	A, E, H	
5014	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5015	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%.
5016	TSUGA CANADENSIS	A, H	
5017	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%.
5018	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5019	TURNERA DIFFUSA	A, E, H	Arbutin is a mandatory component of Turnera diffusa. The concentration of arbutin in

			the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
5020	TURNIP	E	
5021	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than 25%.
5022	TYPHA ANGUSTIFOLIA	A, H	
5023	TYPHA LATIFOLIA	A, H	
5024	TYPHONIUM GIGANTEUM	A, H	
5025	TYROSINE	A, E	