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**
3634	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%.
3635	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%.
3636	PADIMATE O	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 8%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and

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			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3637	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%.
3638	PAEONIA LACTIFLORA	A, E, H	
3639	PAEONIA OBOVATA	A, H	
3640	PAEONIA SUFFRUTICOSA	A, E, H	
3641	PAEONIA VEITCHII	A, H	
3642	PALIURUS SPINA-CHRISTI	A, H	
3643	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3644	PALM FRUIT OIL	A, E, H	
3645	PALM GLYCERIDES	E	
3646	PALM KERNEL OIL	A, E, H	
3647	PALM TOCOTRIENOLS COMPLEX	A, H	
3648	PALMARIA PALMATA	A, H	
3649	PALMAROSA OIL	A, E, H	
3650	PALMIDROL	A	Only permitted for use in medicines limited to oral routes of administration. The maximum recommended daily dose of the medicine must not provide more than 600 mg of palmidrol. The following warning statements (or words to the same effect) are required on the medicine label: - (ANALG) 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.'

			- (ADULT) 'Adults only.' - (21DAYS) 'Not to be used for more than 21 consecutive days.'
3651	PALMITIC ACID	E	
3652	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3653	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%.
3654	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%
3655	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%.
3656	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%.
3657	PALMITOYL TETRAPEPTIDE-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.001%.

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3658	PANAX GINSENG	A, E, H	
3659	PANAX JAPONICUS	A, H	
3660	PANAX NOTOGINSENG	A, H	
3661	PANAX PSEUDOGINSENG	A, H	
3662	PANAX QUINQUEFOLIUS	A, H	
3663	PANICUM MILIACEUM	A, H	
3664	PANTETHINE	E	Only for use in topical medicines for dermal application.
3665	PANTHENOL	A, E	
3666	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3667	PANTOLACTONE	E	
3668	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3669	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%.
3670	PAPAIN	A, E	
3671	PAPER	E	Only for use in topical medicines for dermal application.
3672	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%.
3673	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%.
3674	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%.
3675	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%.
3676	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%.
3677	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3678	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%.
3679	PARA-ETHYL CRESOXYACETATE	E	Para-ethyl cresoxyacetate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing para-ethyl cresoxyacetate must not be more than 1% of the total medicine.
3680	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%.
3681	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%.

3682	PARA-HYDROXYBENZOIC ACID	E	
3683	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%.
3684	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%.
3685	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%.
3686	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

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			fragrance concentration in a medicine must be no more 1%.
3687	PARA-PROPYL ANISOLE	E	Para-propyl anisole must only be included in medicines when in combination with other permitted ingredients as a fragrance and/or flavour proprietary excipient formulation. The total concentration of fragrance proprietary excipient formulations containing para-propyl anisole must not be more than 1% of the total medicine. The total concentration of flavour proprietary excipient formulations containing para-propyl anisole must not be more than 5% of the total medicine.
3688	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%.
3689	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%.
3690	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%.
3691	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%.
3692	PARAMERIA LAEVIGATA	A, H	
3693	PARIETARIA JUDAICA	A, H	
3694	PARIS POLYPHYLLA	A, H	
3695	PARIS QUADRIFOLIA	A, H	
3696	PARSLEY HERB DRY	A, E, H	
3697	PARSLEY HERB OIL	A, E, H	
3698	PARSLEY HERB POWDER	A, E, H	
3699	PARSLEY SEED OIL	A, E, H	
3700	PARTHENOCISSUS TRICUSPIDATA	A, H	
3701	PARTIALLY DEHYDRATED LIQUID SORBITOL	E	Sorbitol is a mandatory component of partially dehydrated liquid sorbitol. Permitted for use only as part of the capsule in medicines where the dosage form is a soft capsule.
3702	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%.
3703	PARTIALLY REFINED	E	Only for use in topical medicines

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	PORPHYRA YEZOENSIS CYTOPLASM EXTRACT		for dermal 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%.
3704	PASPALUM NOTATUM	A, H	
3705	PASSIFLORA CAERULEA	A, H	
3706	PASSIFLORA EDULIS	E	
3707	PASSIFLORA HERB DRY	A, H	
3708	PASSIFLORA INCARNATA	A, E, H	
3709	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%.
3710	PATENT BLUE V	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3711	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3712	PATRINIA SCABIOSIFOLIA	A, H	
3713	PATRINIA VILLOSA	A, H	
3714	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. When for internal use or oral

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

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			- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
3715	PAULLINIA PINNATA	A, H	
3716	PAWPAW	E	
3717	PEA	E	
3718	PEA STARCH	E	
3719	PEACH	E	
3720	PEAR	E	
3721	PECAN	E	
3722	PECTIN	A, E	
3723	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%.
3724	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3725	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3726	PEG-12 DILAURATE	E	
3727	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%.

3728	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3729	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3730	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3731	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3732	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%.
3733	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3734	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3735	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3736	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3737	PEG-25 PABA	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label:

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			- (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).
3738	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3739	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3740	PEG-35 CASTOR OIL	E	
3741	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3742	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%.
3743	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3744	PEG-40 CASTOR OIL	E	
3745	PEG-40 HYDROGENATED CASTOR OIL	E	
3746	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%.
3747	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3748	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3749	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3750	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3751	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%.
3752	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3753	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%.

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3754	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%.
3755	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3756	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3757	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3758	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3759	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3760	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%.
3761	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%.
3762	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%.
3763	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3764	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.
3765	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3766	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3767	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%.
3768	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%.
3769	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%.

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3770	PELARGONIUM GRAVEOLENS	A, E, H	
3771	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%.
3772	PELTIGERA CANINA	A, H	
3773	PENICILLIUM EXPANSUM	A, H	
3774	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.
3775	PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.018%
3776	PENTAERYTHRITYL	E	Only for use in topical medicines

	TETRAISOSTEARATE		for dermal 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%.
3777	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3778	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%.
3779	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%.
3780	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%.
3781	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

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			must be no more than 5%.
3782	PEPPER BLACK	E, H	
3783	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%.
3784	PEPPERMINT AMERICAN EXT.	E	Menthol is a mandatory component of peppermint american ext. When the medicine is for topical use for dermal application: a) the medicine must not be intended for use in the eye or on damaged skin; b) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; c) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). d) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. e) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following

			warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3785	PEPPERMINT LEAF DRY	A, E, H	Menthol is a mandatory component of peppermint leaf dry. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:

			– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3786	PEPPERMINT LEAF POWDER	A, E, H	Menthol is a mandatory component of peppermint leaf powder. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high

			concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3787	PEPPERMINT OIL	A, E, H	Menthol is a mandatory component of peppermint oil. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.

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			When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3788	PEPPERMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. The total fragrance proprietary excipient formulation in a medicine must be no more 1%. Menthol is a mandatory component of peppermint oil terpeneless. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a

			large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3789	PEPPERMINT OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. Menthol is a mandatory component of peppermint oil terpenes and terpenoids. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). iv) if the medicine delivers more than 1% total menthol when

			administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3790	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3791	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%.
3792	PERILLA FRUTESCENS	A, E, H	
3793	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%.
3794	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%.
3795	PERMETHRIN	E	The total concentration of permethrin in the medicine must not be more than 2%.
3796	PERSEA AMERICANA	A, E, H	
3797	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%.
3798	PERSICARIA CHINENSIS	A, H	
3799	PERSICARIA TINCTORIA	A, H	
3800	PERU BALSAM	A, E, H	
3801	PERU BALSAM OIL	A, E, H	
3802	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

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			flavour concentration in a medicine must be no more than 5%
3803	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%.
3804	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%.
3805	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.
3806	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%.
3807	PETROSELINUM CRISPUM	A, E, H	
3808	PEUCEDANUM PRAERUPTORUM	A, E, H	
3809	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).
3810	PHALARIS ARUNDINACEA	A, H	
3811	PHALARIS CANARIENSIS	A, H	
3812	PHASEOLUS COCCINEUS	A, H	
3813	PHASEOLUS VULGARIS	A, H	
3814	PHELLINUS ROBINIAE	A, E, H	
3815	PHELLODENDRON AMURENSE	A, E, H	
3816	PHELLODENDRON CHINENSE	A, H	
3817	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3818	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

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			medicine must be no more 1%.
3819	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%.
3820	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%.
3821	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%.
3822	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%
3823	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%.
3824	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%.
3825	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%.
3826	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%.
3827	PHENETHYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			fragrance. If used in a flavour the total flavour concentration in 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%.
3828	PHENOL	E	Only for use in topical medicines for dermal application. The concentration of phenol in the medicine must be no more than 1%.
3829	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%.
3830	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The concentration of phenoxyethanol in the preparation must not exceed 15%.
3831	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%.
3832	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.

3833	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3834	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3835	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%.
3836	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%.
3837	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%.
3838	PHENYLACETIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3839	PHENYLALANINE	A, E	When the maximum recommended daily dose of the medicine provides more than 500 mg phenylalanine, the following warning statement is required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.
3840	PHENYLBENZIMIDAZOLE SULFONIC ACID	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 4%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3841	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%.
3842	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%.
3843	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%.
3844	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%.
3845	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%.
3846	PHENYLETHYL METHYLETHYL	E	Permitted for use only in

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	CARBINOL		combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3847	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%.
3848	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%.
3849	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%.
3850	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%.
3851	PHLEUM PRATENSE	A, H	

3852	PHLOXINE B	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3853	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3854	PHOENIX DACTYLIFERA	A, E, H	
3855	PHOSPHATIDYL CHOLINE	E	
3856	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%.
3857	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3858	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient. The total concentration of phosphorus in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.
3859	PHOTINIA SERRULATA	A, H	
3860	PHRAGMITES AUSTRALIS	A, H	
3861	PHYLLANTHUS AMARUS	A, H	
3862	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
3863	PHYLLOSTACHYS NIGRA	A, E, H	
3864	PHYSALIS ALKEKENGI	A, H	
3865	PHYSALIS PUBESCENS	A, H	
3866	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.

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3867	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%.
3868	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3869	PHYTOMENADIONE	A, E	
3870	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%.
3871	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%.
3872	PICEA ABIES	A, H	
3873	PICEA MARIANA	A, H	
3874	PICRASMA EXCELSA	A, E, H	
3875	PICRORRHIZA KURROA	A, E, H	
3876	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%.
3877	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%.
3878	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%.
3879	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3880	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3881	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3882	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3883	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.
3884	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3885	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3886	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.

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3887	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%.
3888	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%.
3889	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%.
3890	PIMENTA FRUIT OIL	A, E, H	
3891	PIMENTA LEAF OIL	A, E, H	
3892	PIMENTA OFFICINALIS	A, E, H	
3893	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'.
3894	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).
3895	PIMPINELLA SAXIFRAGA	A, E, H	
3896	PINE NEEDLE OIL SCOTCH	A, E, H	
3897	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%.
3898	PINE OIL AROMATIC	A, E, H	

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3899	PINE OIL PUMILIO	A, E, H	
3900	PINEAPPLE	E	
3901	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%.
3902	PINELLIA TERNATA	A, H	
3903	PINUS CONTORTA	A, E, H	
3904	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%.
3905	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%.
3906	PINUS MONTICOLA	A, E, H	
3907	PINUS MUGO	A, E, H	
3908	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%.
3909	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%.
3910	PINUS PONDEROSA	A, E, H	
3911	PINUS RADIATA	A, E, H	
3912	PINUS STROBUS	A, E, H	
3913	PINUS SYLVESTRIS	A, E, H	
3914	PINUS TABULIFORMIS	A, E, H	
3915	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%.
3916	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%.
3917	PIPER CHABA	A, E, H	
3918	PIPER CUBEBA	A, E, H	
3919	PIPER KADSURA	A, E, H	
3920	PIPER LONGUM	A, E, H	
3921	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.
3922	PIPER NIGRUM	A, E, H	
3923	PIPER SARMENTOSUM	A, E, H	
3924	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%.
3925	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%.
3926	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%.
3927	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%.
3928	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application.
3929	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.

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			The concentration in the medicine must be no more than 1% in wash-on/wash-off medicines and 0.5% in leave-on medicines.
3930	PISCIDIA PISCIPULA	A, E, H	
3931	PISTACIA LENTISCUS	A, E, H	
3932	PISUM SATIVUM	A, E, H	
3933	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3934	PLANTAGO AFRA	A, E, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3935	PLANTAGO ARENARIA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3936	PLANTAGO ASIATICA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3937	PLANTAGO LANCEOLATA	A, E, H	The medicine requires the following warning statement on the medicine label: - (CHILD5) 'Use in children under 3 years is not recommended' When a dose for children is stated and the plant part is flower, seed or pollen, the following warning

			statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3938	PLANTAGO MAJOR	A, E, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3939	PLANTAGO OVATA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3940	PLANTAGO SEED DRY	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3941	PLATANUS OCCIDENTALIS	A, E, H	
3942	PLATANUS RACEMOSA	A, H	
3943	PLATANUS × HISPANICA	A, H	
3944	PLATYCODON GRANDIFLORUS	A, E, H	
3945	PLECTRANTHUS BARBATUS	A, E, H	
3946	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%.

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3947	PLUM	E	
3948	PLUMBAGO EUROPAEA	A, H	
3949	PLUMERIA ALBA	A, E, H	
3950	PLUMERIA RUBRA	A, E, H	
3951	POA NEMORALIS	A, H	
3952	POA PRATENSIS	A, H	
3953	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%.
3954	POGOSTEMON CABLIN	A, E, H	
3955	POLACRILIN	E	
3956	POLACRILIN POTASSIUM	E	
3957	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).
3958	POLIGLUSAM	A, E	The average molecular mass of poliglusam must be greater than 2 kilodaltons. When for internal use: (a) the maximum recommended daily dose of the medicine must not provide more than 1750 milligrams poliglusam; and (b) the following warning statement is required on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect). When for internal use and the dosage form is a powdered preparation, the following warning statement is required on the medicine label: - (DNTPOW) 'Do not take powder alone. Mix with food or fluid'. When used as an excipient, only for use in topical medicines for dermal application.
3959	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	When for oral use: (a) the maximum recommended daily dose of the medicine must not provide more than 2000 mg of Poliglusam derived from Aspergillus niger; (b) the following warning statement (or words to the same effect) is required on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce

			the effect of other medication.'; and (c) if the medicine is a powdered dosage form, the following warning statement is also required on the medicine label: - (DNTPOW) 'Do not take powder alone. Mix with food or fluid.' When used as an excipient, Poliglusam derived from Aspergillus niger is only permitted for use in topical medicines for dermal application.
3960	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.
3961	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).
3962	POLOXAMER	E	Only for use in topical medicines for dermal application.
3963	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%.
3964	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%.
3965	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%.
3966	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%.
3967	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%.
3968	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%.
3969	POLYACRYLIC ACID	E	
3970	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3971	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%.
3972	POLYBUTADIENE	E	Only for use as part of an adhesive in topical medicines for dermal application.

3973	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3974	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%.
3975	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%.
3976	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%.
3977	POLYDEXTROSE	E	
3978	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%.
3979	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%

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3980	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%.
3981	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%.
3982	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%.
3983	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%.
3984	POLYETHYLENE	E	
3985	POLYGALA CHINENSIS	A, H	
3986	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.
3987	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
3988	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.

3989	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%.
3990	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%.
3991	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%.
3992	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3993	POLYGLYCERYL-2 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 3%.
3994	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.

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			The concentration in the medicine must not be more than 5%.
3995	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3996	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%.
3997	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
3998	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%.
3999	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%.
4000	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%.
4001	POLYGLYCERYL-3 POLYRICINOLEATE	E	
4002	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

	CROSSPOLYMER		for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4003	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%.
4004	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%.
4005	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
4006	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%.
4007	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
4008	POLYGONATUM MULTIFLORUM	A, H	
4009	POLYGONATUM OFFICINALE	A, H	
4010	POLYGONATUM SIBIRICUM	A, E, H	
4011	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.

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			When used as an excipient, the concentration in the medicine must be no more than 0.16%.
4012	POLYGONUM BISTORTA	A, H	
4013	POLYGONUM ODORATUM	A, H	
4014	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
4015	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.
4016	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
4017	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%.
4018	POLYMETHACRYLIC ACID	E	
4019	POLYMETHYL METHACRYLATE	E	Methyl methacrylate is a mandatory component of polymethyl methacrylate. Only for use in topical medicines for dermal application. The total concentration of methyl methacrylate as residual monomer

			in the medicine must not be more than 1%.
4020	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%.
4021	POLYPORUS UMBELLATUS	A, H	
4022	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
4023	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%.
4024	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
4025	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4026	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%.
4027	POLYQUATERNIUM-24	E	Only for use in topical medicines

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			for dermal application.
4028	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
4029	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%.
4030	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%.
4031	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%.
4032	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%.
4033	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
4034	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%

4035	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%.
4036	POLYSILICONE-15	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4037	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%.
4038	POLYSORBATE 20	E	
4039	POLYSORBATE 40	E	
4040	POLYSORBATE 60	E	
4041	POLYSORBATE 65	E	
4042	POLYSORBATE 80	E	
4043	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4044	POLYSTYRENE	E	Only for use as part of an adhesive

			in topical medicines for dermal application.
4045	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%.
4046	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.
4047	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%.
4048	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4049	POLYVINYL ACETATE PHTHALATE	E	
4050	POLYVINYL ALCOHOL	E	
4051	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4052	POMEGRANATE	E	
4053	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4054	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.
4055	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%.
4056	PONTEDERIA CRASSIPES	A, H	
4057	POPPY SEED	E, H	
4058	POPPY SEED OIL	E, H	
4059	POPULUS ALBA	A, H	
4060	POPULUS BALSAMIIFERA	A, E, H	
4061	POPULUS CANDICANS	A, H	
4062	POPULUS DELTOIDES	A, H	
4063	POPULUS NIGRA	A, H	
4064	POPULUS TREMULA	A, H	
4065	POPULUS TREMULOIDES	A, H	
4066	PORCINE	H	Only for use as an active homoeopathic ingredient.
4067	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%.
4068	PORTULACA OLERACEA	A, E, H	
4069	POTABLE WATER	E	
4070	POTASSIUM ACETATE	E	
4071	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4072	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory

			component of potassium ascorbate.
4073	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4074	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4075	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.
4076	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.
4077	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.
4078	POTASSIUM BICARBONATE	E	
4079	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.

			The total concentration of potassium bromide in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4080	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.
4081	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4082	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: - (POTAS1) 'If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and (c) except when the medicine is for use as oral rehydration therapy, the amount of potassium chloride per dosage unit must not be more than 550 mg. Medicines containing potassium chloride for use as oral rehydration therapy, are subject to the following conditions: (a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; (b) the sodium, potassium and glucose content, and total

			osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and (c) the following warning statements are required on the medicine label: - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration of potassium chloride in the medicine must not be more than 3.75%.
4083	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.
4084	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%.
4085	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%.
4086	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.

4087	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.
4088	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.
4089	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.
4090	POTASSIUM HYDROXYCITRATE	A, H	
4091	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.
4092	POTASSIUM IODIDE	A, E, H	Iodine is a mandatory component of potassium iodide.

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			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%.
4093	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%.
4094	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%.
4095	POTASSIUM NITRATE	A, H	Only for dental use. The concentration in the medicine must be no more than 5%.
4096	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.
4097	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%.
4098	POTASSIUM SORBATE	E	
4099	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%.
4100	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4101	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.
4102	POTATO STARCH	E	
4103	POTENTILLA ANSERINA	A, H	
4104	POTENTILLA CHINENSIS	A, H	
4105	POTENTILLA DISCOLOR	A, H	
4106	POTENTILLA ERECTA	A, E, H	
4107	POTENTILLA REPTANS	A, H	

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4108	POTERIUM OFFICINALE	A, E, H	
4109	POTERIUM SANGUISORBA	A, H	
4110	POVIDONE	E	
4111	POWDERED CELLULOSE	E	
4112	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%.
4113	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%.
4114	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%.
4115	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%.
4116	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%.

4117	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4118	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%.
4119	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4120	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%.
4121	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4122	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%.
4123	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4124	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4125	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4126	PRALINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4127	PREGELATINISED MAIZE STARCH	E	
4128	PREGELATINISED POTATO STARCH	E	
4129	PREGELATINISED RICE STARCH	E	
4130	PREGELATINISED STARCH	E	
4131	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4132	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%.
4133	PRICKLY ASH BARK DRY	A, H	
4134	PRICKLY ASH BARK POWDER	A, H	
4135	PRIMULA VERIS	A, E, H	
4136	PRIMULA VULGARIS	A, E, H	
4137	PRINSEPIA UNIFLORA	A, H	
4138	PROBOSCIDEA PARVIFLORA	A, H	
4139	PROGESTERONE	H	Only for use as an active homoeopathic ingredient. The total concentration of progesterone in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.

4140	PROLINE	A, E	
4141	PROPAN-1-OL	E	Only for use in: - topical medicines for dermal application; or - in combination with other permitted ingredients as a flavour proprietary excipient formulation. The concentration of propan-1-ol in the medicine must not be more than 18%. When used in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation, the total flavour proprietary excipient formulation in a medicine must not be more than 5%.
4142	PROPANE	E	Only for use as an excipient propellant ingredient.
4143	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%.
4144	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%.
4145	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%.
4146	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%.
4147	PROPIONYLLEVOCARNITINE HYDROCHLORIDE	A, H	
4148	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.'

4149	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.'
4150	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.'
4151	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.'
4152	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.'
4153	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.'
4154	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%.
4155	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%.
4156	PROPYL GALLATE	E	
4157	PROPYL HYDROXYBENZOATE	E	
4158	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4159	PROPYLENE GLYCOL	E	
4160	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%.
4161	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%.
4162	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%.
4163	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4164	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4165	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4166	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%.
4167	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4168	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4169	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.

4170	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4171	PROSOPIS JULIFLORA	A, H	
4172	PROTEASE	A	Must be derived from Aspergillus oryzae or Aspergillus niger.
4173	PROTEIN HYDROLYSATE	E	
4174	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%.
4175	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%.
4176	PRUNELLA VULGARIS	A, H	
4177	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%.
4178	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%.
4179	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%.
4180	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%.
4181	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%.
4182	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%.
4183	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%.
4184	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%.
4185	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%.
4186	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%.

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			The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4187	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%.
4188	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%.
4189	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%.
4190	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%.
4191	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%.
4192	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4193	PSEUDOCYDONIA SINENSIS	A, H	
4194	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4195	PSEUDOTSUGA MENZIESII	A, H	
4196	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4197	PSIDIUM GUAJAVA	A, E, H	
4198	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4199	PSYLLIUM HUSK DRY	A, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4200	PSYLLIUM HUSK POWDER	A, E, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4201	PSYLLIUM SEED DRY	A, E, H	When a dose for children is stated the following warning statement is

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			required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4202	PTELEA TRIFOLIATA	A, H	
4203	PTEROCARPUS MARSUPIUM	A, H	
4204	PTEROCARPUS SANTALINUS	A, E, H	
4205	PUERARIA LOBATA	A, E, H	
4206	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4207	PULLULAN	E	
4208	PUMICE	E	
4209	PUMPKIN	E	
4210	PUMPKIN SEED OIL	E, H	
4211	PUNICA GRANATUM	A, E, H	
4212	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4213	PURIFIED HONEY	A, E	When the route of administration is oral, the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).
4214	PURIFIED SILICEOUS EARTH	E, H	
4215	PURIFIED TALC	E	
4216	PURIFIED WATER	E	
4217	PVM/MA COPOLYMER	E	
4218	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4219	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4220	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.

4221	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).
4222	PYRIDOXAL 5-PHOSPHATE	A, E	Pyridoxine is a mandatory component of pyridoxal 5-phosphate. The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate. The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop

			taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].
4223	PYRIDOXAL 5-PHOSPHATE MONOHYDRATE	A	Pyridoxine is a mandatory component of pyridoxal 5-phosphate monohydrate. The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate. The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'

4224	PYRIDOXINE HYDROCHLORIDE	A, E, H	When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of pyridoxine hydrochloride. The percentage of pyridoxine from pyridoxine hydrochloride should be calculated based on the molecular weight of pyridoxine hydrochloride. The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
4225	PYROGLUTAMIC ACID	E	
4226	PYROLA DECORATA	A, H	

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4227	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%.
4228	PYRROSIA LINGUA	A, H	
4229	PYRROSIA PETIOLOSA	A, H	
4230	PYRROSIA SHEARERI	A, H	
4231	PYRUS COMMUNIS	A, E, H	Beta-arbutin is a mandatory component of Pyrus communis. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4232	PYRUS PYRIFOLIA	A, H	Beta-arbutin is a mandatory component of Pyrus pyrifolia. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application

			exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4233	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%.
4234	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%.
4235	QUASSIA AMARA	A, E, H	
4236	QUASSIA WOOD JAMAICAN DRY	A, H	
4237	QUASSIA WOOD JAMAICAN POWDER	A, H	
4238	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4239	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines

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			for dermal application.
4240	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4241	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.
4242	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%.
4243	QUERCETIN	A	
4244	QUERCETIN DIHYDRATE	A	
4245	QUERCUS ACUTISSIMA	A, H	
4246	QUERCUS ALBA	A, E, H	
4247	QUERCUS PALUSTRIS	A, H	
4248	QUERCUS ROBUR	A, H	
4249	QUERCUS RUBRA	A, H	
4250	QUERCUS VIRGINIANA	A, H	
4251	QUILLAIA DRY	A, H	
4252	QUILLAIA POWDER	A, E, H	
4253	QUILLAJA SAPONARIA	A, H	
4254	QUINCE	E	
4255	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.
4256	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.
4257	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4258	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4259	QUISQUALIS INDICA	A, H	
4260	R-ALPHA LIPOIC ACID	A	
4261	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%.
4262	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%.

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	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.
4263	RADISH	E	
4264	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%.
4265	RANUNCULUS BULBOSUS	A, H	
4266	RANUNCULUS FICARIA	A, H	
4267	RANUNCULUS TERNATUS	A, H	
4268	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%.
4269	RAPHANUS SATIVUS	A, H	
4270	RASPBERRY	E	
4271	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%.
4272	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%.

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4273	RASPBERRY FRUIT EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4274	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%.
4275	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%.
4276	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%.
4277	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%.
4278	RED 27	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. The concentration in the medicine must be no more than 0.5%.
4279	RED 27 ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. The concentration in the medicine

			must be no more than 0.5%.
4280	RED ANT	H	Only for use as an active homoeopathic ingredient.
4281	RED CLOVER FLOWER DRY	A, H	
4282	RED CLOVER FLOWER POWDER	A, H	
4283	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4284	RED DEER	A	
4285	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4286	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4287	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4288	REHMANNIA GLUTINOSA	A, E, H	
4289	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%.
4290	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%.
4291	RESORCINOL DIMETHYLETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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			flavour concentration in a medicine must be no more than 5%.
4292	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’.
4293	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.’
4294	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

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			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.'
4295	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.'
4296	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4297	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%.
4298	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'.
4299	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

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			- (LAX2) 'Prolonged use may cause serious bowel problems'.
4300	RHATANY ROOT DRY	A, H	
4301	RHATANY ROOT POWDER	A, H	
4302	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'.
4303	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’.
4304	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'.
4305	RHEUM TANGUTICUM	A, H	The plant part must not be leaf.

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		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'.
4306	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4307	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%.
4308	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%.
4309	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.
4310	RHODODENDRON AUREUM	A, H	

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4311	RHODODENDRON FERRUGINEUM	A, H	Beta-arbutin is a mandatory component of Rhododendron ferrugineum. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4312	RHODODENDRON GROENLANDICUM	A, H	
4313	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4314	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'.
4315	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'.
4316	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'.
4317	RHUS AROMATICA	A, E, H	
4318	RHUS CHINENSIS	A, H	
4319	RHUS GLABRA	A, E, H	
4320	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4321	RIBES GROSSULARIA	A, E, H	
4322	RIBES NIGRUM	A, E, H	
4323	RIBOFLAVIN	A, E	
4324	RIBOFLAVIN SODIUM PHOSPHATE	A, E	
4325	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4326	RIBOFLAVINE	A, E	
4327	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4328	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4329	RIBOSE	A	Only for use in oral medicines.

4330	RICE	E	
4331	RICE BRAN	E	
4332	RICE BRAN OIL	E	
4333	RICE BRAN WAX	A, E, H	
4334	RICE STARCH	E	
4335	RICE VINEGAR	E	
4336	RICE WINE	E	Ethanol is a mandatory component of rice wine.
4337	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4338	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4339	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.
4340	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4341	ROSA ARVENSIS	A, E, H	
4342	ROSA CANINA	A, E, H	
4343	ROSA CYMOSA	A, E, H	
4344	ROSA EGLANTERIA	A, E, H	
4345	ROSA GALLICA	A, E, H	
4346	ROSA LAEVIGATA	A, E, H	
4347	ROSA MULTIFLORA	A, E, H	
4348	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%.

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4349	ROSA RUGOSA	A, E, H	
4350	ROSA VILLOSA	A, E, H	
4351	ROSA X CENTIFOLIA	A, E, H	
4352	ROSA X DAMASCENA	A, E, H	
4353	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%.
4354	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%.
4355	ROSE FRUIT FRESH	A, E, H	
4356	ROSE HIP	E	
4357	ROSE OIL	A, E, H	
4358	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%.
4359	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%.
4360	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.
4361	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'.
4362	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'.
4363	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'.
4364	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4365	RUBIA CORDIFOLIA	A, H	
4366	RUBIA TINCTORUM	A, H	
4367	RUBUS CHINGII	A, H	
4368	RUBUS CORCHORIFOLIUS	A, H	
4369	RUBUS COREANUS	A, E, H	
4370	RUBUS FRUTICOSUS	A, E, H	
4371	RUBUS IDAEUS	A, E, H	
4372	RUBUS OCCIDENTALIS	A, E, H	
4373	RUBUS PARVIFOLIUS	A, H	
4374	RUBUS ROSIFOLIUS	A, H	
4375	RUDBECKIA HIRTA	A, H	
4376	RUE OIL	A, H	
4377	RUM	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4378	RUMEX ACETOSA	A, H	
4379	RUMEX ACETOSELLA	A, H	
4380	RUMEX CONGLOMERATUS	A, H	
4381	RUMEX CRISPUS	A, E, H	
4382	RUMEX PULCHER	A, H	
4383	RUMEX SCUTATUS	A, H	
4384	RUSCUS ACULEATUS	A, H	
4385	RUTA GRAVEOLENS	A, E, H	
4386	RUTOSIDE	A, E	
4387	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4388	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.
4389	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%.
4390	SABINENE	E	Sabinene must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing sabinene must not be more than 5% of the total

			medicine.
4391	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%.
4392	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%.
4393	SACCHARIN	E	
4394	SACCHARIN SODIUM	E	
4395	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4396	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4397	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%.
4398	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4399	SACCHARUM OFFICINARUM	A, E, H	
4400	SAFFLOWER OIL	A, E, H	
4401	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4402	SAGE LEAF DRY	A, E, H	Thujone is a mandatory

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			component of Sage leaf dry. The concentration of thujone in the medicine must be no more than 4%.
4403	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%.
4404	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'
4405	SAGE OIL SPANISH	A, E, H	
4406	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%.
4407	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%.
4408	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4409	SALIX ALBA	A, E, H	
4410	SALIX DAPHNOIDES	A, H	
4411	SALIX DISCOLOR	A, H	
4412	SALIX FRAGILIS	A, H	
4413	SALIX NIGRA	A, H	
4414	SALIX PURPUREA	A, H	
4415	SALSOLA KALI	A, H	
4416	SALVIA CHINENSIS	A, H	
4417	SALVIA FRUTICOSA	A, H	
4418	SALVIA HISPANICA	A, E, H	
4419	SALVIA LAVANDULAEFOLIA	A, H	
4420	SALVIA MILTIORRHIZA	A, H	
4421	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%.
4422	SALVIA SCLAREA	A, E, H	
4423	SAMBUCUS CANADENSIS	A, H	
4424	SAMBUCUS EBULUS	A, H	
4425	SAMBUCUS NIGRA	A, E, H	
4426	SANDALWOOD OIL EAST INDIAN	A, E, H	
4427	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.

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4428	SANICULA EUROPAEA	A, H	
4429	SANTALUM ALBUM	A, E, H	
4430	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.
4431	SAPINDUS MUKOROSSI	A, H	
4432	SAPONARIA OFFICINALIS	A, H	
4433	SAPOSHNIKOVIA DIVARICATA	A, H	
4434	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%.
4435	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.
4436	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.
4437	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%.
4438	SATUREIA HORTENSIS	A, H	
4439	SATUREIA MONTANA	A, H	
4440	SAUROPUS SPATULIFOLIUS	A, H	
4441	SAURURUS CHINENSIS	A, H	
4442	SAUSSUREA COSTUS	A, H	
4443	SAVORY OIL SUMMER	A, H	
4444	SAXIFRAGA GRANULATA	A, E, H	
4445	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%.
4446	SCAPHIUM SCAPHIGERUM	A, H	
4447	SCHEFFLERA HEPTAPHYLLA	A, H	
4448	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4449	SCHINUS MOLLE	A, H	
4450	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%.

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4451	SCHISANDRA CHINENSIS	A, E, H	
4452	SCHIZONEPETA TENUIFOLIA	A, E, H	
4453	SCHOENOCAULON OFFICINALE	A, H	The maximum recommended daily dose of the medicine must not contain more than the equivalent of 1 mg of the dry herbal material. The concentration of total alkaloids of Schoenocaulon officinale in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4454	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%.
4455	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%.
4456	SCLERANTHUS ANNUUS	A, H	
4457	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4458	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%.
4459	SCROPHULARIA NINGPOENSIS	A, H	
4460	SCROPHULARIA NODOSA	A, H	
4461	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	

4462	SCUTELLARIA BAICALENSIS	A, E, H	
4463	SCUTELLARIA BARBATA	A, H	
4464	SCUTELLARIA LATERIFLORA	A, E, H	
4465	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%.
4466	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%.
4467	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%.
4468	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.
4469	SEDUM ACRE	A, H	
4470	SELAGINELLA TAMARISCINA	A, H	
4471	SELENICEREUS GRANDIFLORUS	A, E, H	
4472	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.

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			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.'
4473	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.'
4474	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.’
4475	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4476	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.
4477	SEMOLINA	E	
4478	SEMPERVIVUM TECTORUM	A, H	
4479	SENEGA ROOT DRY	A, H	
4480	SENEGA ROOT POWDER	A, H	
4481	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'.
4482	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'.
4483	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'.
4484	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'.
4485	SENNA FRUIT TINNEVELLY POWDER	A, H	When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect).

			When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4486	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'.
4487	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'.

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4488	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'.
4489	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'.
4490	SEPIA	H	Only for use as an active homoeopathic ingredient. The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
4491	SEQUOIA SEMPERVIRENS	A, H	
4492	SEQUOIADENDRON GIGANTEUM	A, H	
4493	SERENOA REPENS	A, H	
4494	SERINE	A, E	
4495	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4496	SESAME OIL	A, E, H	
4497	SESAMUM INDICUM	A, E, H	
4498	SETARIA ITALICA	A, H	
4499	SHARK CALCIUM	A	

	CHONDROITIN SULFATE		
4500	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)
4501	SHARK CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
4502	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4503	SHARK SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
4504	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.'
4505	SHEA BUTTER	E	
4506	SHEA BUTTER ETHYL ESTERS	E	Shea butter ethyl esters must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin. The total concentration of shea butter ethyl esters in the medicine must not be more than 30%.

4507	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4508	SHELLAC	E	
4509	SHEPHERD'S PURSE HERB DRY	A, H	
4510	SHEPHERD'S PURSE HERB POWDER	A, H	
4511	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%.
4512	SIGESBECKIA ORIENTALIS	A, E, H	
4513	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%.
4514	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%.
4515	SILICA SILYLATE	E	Only for use in topical medicines for dermal application.
4516	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4517	SILICON DIOXIDE	A, E, H	Only for use when the route of

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			administration is other than inhalation.
4518	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).
4519	SILVER	H	Only for use as an active homoeopathic ingredient. When for external use, the total concentration of silver in the medicine must not be more than 1%. When for oral use: (a) the total concentration of silver in the medicine must not be more than 0.3%; and (b) the following warning statement is required on the medicine label: - 'Overuse may stain skin or mouth.' (or words to that effect).
4520	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%.
4521	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4522	SILYBUM MARIANUM	A, E, H	
4523	SIMABA CEDRON	A, H	
4524	SIMETHICONE	E	
4525	SIMMONDSIA CHINENSIS	A, E, H	
4526	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%.
4527	SINAPIS ARVENSIS	A, H	
4528	SINOMENIUM ACUTUM	A, H	
4529	SIPHONESTEGIA CHINENSIS	A, H	
4530	SIRAITIA GROSVENORII	A, E, H	
4531	SISYMBRIUM OFFICINALE	A, H	
4532	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%.
4533	SKIPJACK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of Skipjack-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.

			When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
4534	SLIPPERY ELM BARK DRY	A, H	
4535	SLIPPERY ELM BARK POWDER	A, E, H	
4536	SMILAX ARISTOLOCHIIFOLIA	A, H	
4537	SMILAX CHINA	A, H	

4538	SMILAX GLABRA	A, H	
4539	SMILAX OFFICINALIS	A, E, H	
4540	SMILAX ORNATA	A, E, H	
4541	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%.
4542	SODIUM ACETATE	E	
4543	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%.
4544	SODIUM ACID CITRATE	A, E, H	When sodium acid citrate is used as an active ingredient, only for use in oral medicines.
4545	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%.
4546	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).
4547	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).
4548	SODIUM ALGINATE	E	
4549	SODIUM ASCORBATE	A, E, H	
4550	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%.
4551	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%.
4552	SODIUM BENZOATE	E	
4553	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
4554	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4555	SODIUM BICARBONATE	A, E	When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms. Medicines containing sodium bicarbonate for use as oral rehydration therapy are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force

			or existing from time to time, for Oral Rehydration Salts; b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.' c) the following warning statements are required on the medicine label: - (UOAD) 'Use only as directed.' - (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice (or words to that effect).' - (DIAR3) 'If diarrhoea persists, seek medical advice.'
4556	SODIUM BISULFITE	E	
4557	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient. The total concentration of sodium bromide in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4558	SODIUM BUTYRATE	A, E	The route of administration for medicines that contain sodium butyrate must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 1200 mg sodium butyrate.

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			The following warning statement (or words to the same effect) is required on the medicine label: - (ADULT) 'Adults only'.
4559	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4560	SODIUM CALCIUM EDETATE	E	When for oral use, sodium is a mandatory component of sodium calcium edetate. Sodium calcium edetate must only be included in medicines when: (a) the route of administration is limited to topical for dermal use; or (b) in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of sodium calcium edetate in the medicine must not exceed 0.32%. The total concentration of flavour proprietary excipient formulations containing sodium calcium edetate must not be more than 5% of the total medicine.
4561	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4562	SODIUM CARBONATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4563	SODIUM CARBONATE MONOHYDRATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than

			11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4564	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%.
4565	SODIUM CARRAGEENAN	E	
4566	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%.
4567	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4568	SODIUM CHLORIDE	A, E, H	
4569	SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient ingredient: a) only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye; b) the concentration in the medicine must not be more than 0.001%. When used as an active ingredient: a) the route of administration must only be oral; b) the maximum daily dose must

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			not provide more than 1,200 mg of sodium chondroitin sulfate; c) the following statements must be included on the medicine label: - (ADULT) ‘Adults only' (or words to that effect); - (PREGNT) ‘Not recommended for use by pregnant and lactating women’ (or words to that effect).
4570	SODIUM CITRATE	A, E	When for use as an active ingredient, only for oral use.
4571	SODIUM CITRATE DIHYDRATE	A, E	When for use as an active ingredient, only for oral use.
4572	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%.
4573	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4574	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4575	SODIUM CYCLAMATE	E	
4576	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4577	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%.
4578	SODIUM DODECYLBENZENESULFONAT	E	Only for use in topical medicines for dermal application.

	E		The concentration in the medicine must be no more than 30%.
4579	SODIUM ERYTHORBATE	E	
4580	SODIUM ETHYL HYDROXYBENZOATE	E	
4581	SODIUM FLUORIDE	A, E, H	Fluoride is a mandatory component of sodium fluoride. The route of administration must be limited to dental. The dosage form must be limited to pastes, powders and/or gels for dental hygiene. When used as an active ingredient, the medicine is subject to the following conditions: (a) only for use in combination with at least one other active ingredient; and (b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'
4582	SODIUM FUMARATE	E	
4583	SODIUM HYALURONATE	A, E	When for use as an excipient ingredient, sodium hyaluronate must only be used in medicines with a topical route of administration for dermal application. When for use as an active ingredient: (a) the molecular mass of sodium hyaluronate must be between 600

			and 1600 kilodaltons; and (b) sodium hyaluronate must only be used in medicines when the route of administration is limited to: (i) topical for dermal application; or (ii) oral. When for use in a topical medicine for dermal application the concentration of sodium hyaluronate in the medicine must not exceed 2.0%. When for use as an active ingredient and the route of administration is oral: (a) the maximum recommended daily dose must not provide more than 200 milligrams sodium hyaluronate; (b) the recommended duration of use of the medicine must be limited to three months; and (c) the following warning statements (or words to the same effect) are required on the medicine label : - (ADULT) 'Adults only'; and - (PREGNT) ' Not recommended for use by pregnant and lactating women'.
4584	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4585	SODIUM HYDROXIDE	E	The concentration of sodium hydroxide in the medicine must not be more than 5%. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the

			preparation must not exceed 11.5.
4586	SODIUM HYDROXYCITRATE	A	
4587	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%.
4588	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4589	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of sodium hypochlorite. The concentration of chlorine in the medicine must not be more than 4%.
4590	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4591	SODIUM LACTATE	E	
4592	SODIUM LAURETH SULFATE	E	
4593	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%.
4594	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%.
4595	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.

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4596	SODIUM LAURYL PHOSPHATE	E	
4597	SODIUM LAURYL SULFATE	E	
4598	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4599	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4600	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%.
4601	SODIUM METABISULFITE	E	
4602	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%.
4603	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine must be no more than 2%.
4604	SODIUM METHYL HYDROXYBENZOATE	E	
4605	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.
4606	SODIUM MONOFLUOROPHOSPHATE	A	Fluoride is a mandatory component of sodium monofluorophosphate. The route of administration must be limited to dental. The dosage form must be limited to pastes, powders and/or gels for dental hygiene. When sodium monofluorophosphate is used as an active ingredient, it is subject to the following conditions: (a) only for use in combination with at least one other active ingredient; and (b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000 mg/kg, the following warning statements are required on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'
4607	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%.
4608	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4609	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.

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4610	SODIUM PANTOTHENATE	A, E, H	
4611	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4612	SODIUM PERBORATE	A, H	Boron is a mandatory component of sodium perborate. When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron. When used in preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron from all ingredients in the product must not exceed 3500 mg/kg or 3500 mg/L or 0.35%. When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label: - (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label: - (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or - (ADULT) 'Adults only' (or

			words to that effect). When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label: - (BORON) 'Contains boron' (or words to that effect). When the medicine is for topical use for dermal application, the following warning statement is required on the label: - (BROKEN) 'Use on unbroken skin only' (or words to that effect).
4613	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.
4614	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4615	SODIUM POLYACRYLATE STARCH	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 1%.
4616	SODIUM POLYMETAPHOSPHATE	E	
4617	SODIUM PROPIONATE	E	
4618	SODIUM PROPYL HYDROXYBENZOATE	E	
4619	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

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			must be no more than 0.2%.
4620	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.'
4621	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.'
4622	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.'
4623	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.'
4624	SODIUM SILICATE	E	
4625	SODIUM STARCH GLYCOLLATE	E	
4626	SODIUM STARCH GLYCOLLATE TYPE A	E	
4627	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4628	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%.
4629	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

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			must be no more than 2.5%.
4630	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4631	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%.
4632	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4633	SODIUM SULFATE	A, E, H	When it is not intended to be a laxative, the following warning statement is required on the medicine label: - (LAX4) 'Substance may have a laxative effect'.
4634	SODIUM SULFATE DECAHYDRATE	A, E, H	When it is not intended to be a laxative, the following warning statement is required on the medicine label: - (LAX4) 'Substance may have a laxative effect'.
4635	SODIUM SULFITE	E	
4636	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application.
4637	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%.

4638	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.
4639	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.
4640	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%.
4641	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.
4642	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.
4643	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.
4644	SOLIDAGO GIGANTEA	A, H	
4645	SOLIDAGO GIGANTEA MIS	A, E, H	
4646	SOLIDAGO VIRGAUREA	A, E, H	
4647	SOLUBLE MAIZE STARCH	E	
4648	SOLUBLE POTATO STARCH	E	
4649	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4650	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4651	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4652	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%.
4653	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4654	SOPHORA FLAVESCENS	A, E, H	
4655	SOPHORA TONKINENSIS	A, H	
4656	SORBIC ACID	E	
4657	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.

4658	SORBITAN MONO-OLEATE	E	
4659	SORBITAN MONOLAURATE	E	
4660	SORBITAN MONOSTEARATE	E	
4661	SORBITAN OLEATE	E	
4662	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%.
4663	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%.
4664	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4665	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4666	SORBITAN STEARATE	E	
4667	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4668	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.
4669	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.
4670	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.
4671	SORBUS AUCUPARIA	A, H	
4672	SORGHUM	E	
4673	SORGHUM VULGARE	A, H	
4674	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4675	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%.
4676	SOY POLYSACCHARIDE	E	

4677	SOY PROTEIN	E	
4678	SOY STEROL	E	
4679	SOYA BEAN	E	
4680	SOYA OIL	A, E, H	
4681	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%.
4682	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%.
4683	SPARGANIUM STOLONIFERUM	A, H	
4684	SPARTIUM JUNCEUM	A, H	
4685	SPATHOLOBUS SUBERECTUS	A, H	
4686	SPEARMINT OIL	A, E, H	Menthol is a mandatory component of spearmint oil. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the

			directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4687	SPEARMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. Menthol is a mandatory component of spearmint oil terpeneless. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol

			when administered according to the directions for use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4688	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%.
4689	SPIGELIA ANTHELMIA	A, H	
4690	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry

			herbal material.
4691	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.
4692	SPINACH	E	
4693	SPINACIA OLERACEA	A, E, H	
4694	SPIRODELA POLYRRHIZA	A, H	
4695	SPIRULINA	E	
4696	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use as an excipient for oral routes of administration.
4697	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use as an excipient for oral routes of administration.
4698	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%.
4699	SQUALANE	E	Only for use in topical medicines for dermal application.
4700	SQUALENE	A, E	
4701	SQUID OIL	A	Only for use in oral medicines. Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in combination with other

			ingredients in the medicine and be presented in a therapeutic dosage form for therapeutic use. The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
4702	SQUILL DRY	A, H	
4703	SQUILL INDIAN DRY	A, H	
4704	SQUILL INDIAN POWDER	A, H	
4705	SQUILL POWDER	A, H	
4706	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.'
4707	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.'
4708	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.'
4709	STACHYS OFFICINALIS	A, E, H	

4710	STACHYS PALUSTRIS	A, H	
4711	STACHYURUS HIMALAICUS	A, H	
4712	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%.
4713	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4714	STAR ANISE OIL	A, E	When the total concentration of star anise oil in the medicine is more than 50%: (a) the nominal capacity of the container must not be more than 50 mL; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4715	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%.
4716	STARCH SODIUM OCTENYL SUCCINATE	E	
4717	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4718	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.

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4719	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4720	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4721	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4722	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).
4723	STEARETH-10	E	Only for use in topical medicines for dermal application.
4724	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%.
4725	STEARETH-2	E	Only for use in topical medicines for dermal application.
4726	STEARETH-20	E	Only for use in topical medicines for dermal application.
4727	STEARETH-21	E	Only for use in topical medicines for dermal application.
4728	STEARETH-5	E	Only for use in topical medicines for dermal application.

4729	STEARIC ACID	E	
4730	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%.
4731	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%.
4732	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4733	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4734	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4735	STEARYL ALCOHOL	E	
4736	STEARYL BEHENATE	E	Only for use as an excipient ingredient for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 3.5% in the final formulation.
4737	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).
4738	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4739	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4740	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%.
4741	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4742	STELLARIA CHAMAEJASME	A, H	
4743	STELLARIA DICHOTOMA	A, H	
4744	STELLARIA MEDIA	A, E, H	
4745	STEMONA JAPONICA	A, H	
4746	STEMONA SESSILIFOLIA	A, H	
4747	STENOTAPHRUM SECUNDATUM	A, H	
4748	STEPHANIA TETRANDA	A, H	
4749	STERCULIA	A, H	
4750	STERCULIA TRAGACANTHA	A, H	
4751	STERCULIA URENS	A, H	
4752	STEVIA REBAUDIANA	A, E, H	
4753	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4754	STILLINGIA SYLVATICA	A, H	

4755	STORAX PREPARED	A, E, H	
4756	STRAWBERRY	E	
4757	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%.
4758	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'.
4759	STREPTOCOCCUS THERMOPHILUS	A	
4760	STROBILANTHES CUSIA	A, H	
4761	STRONG AMMONIA SOLUTION	E	Ammonia is a mandatory component of strong ammonia solution. The concentration of ammonia in the medicine must be no more than 0.5%. When for internal use, the concentration in the medicine must be no more than 0.25%.
4762	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.

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4763	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4764	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4765	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%.
4766	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%.
4767	STYPHNOLOBIUM JAPONICUM	A, E, H	
4768	STYRALLYL PROPIONATE	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
4769	STYRAX BENZOIN	A, E, H	
4770	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%.
4771	STYRAX PARALLELONEURUM	A, H	
4772	STYRAX TONKINENSIS	A, H	
4773	STYRENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. The total concentration of styrene in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4774	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4775	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%.
4776	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4777	SUCCINIC ACID	E	
4778	SUCRALOSE	E	
4779	SUCROSE	E	
4780	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

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			5%.
4781	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%.
4782	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%.
4783	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4784	SUCROSE LAURATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate.
4785	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.
4786	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4787	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).

4788	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.
4789	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%.
4790	SUDAN III	E	Permitted for use only as a colour for topical use.
4791	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).
4792	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of sugarcane.
4793	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.

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4794	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%.
4795	SULFUR DIOXIDE	E	
4796	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4797	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%.
4798	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%.
4799	SULISOBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

4800	SULISOBENZONE SODIUM	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4801	SUNFLOWER OIL	A, E, H	
4802	SUNFLOWER SEED	E, H	
4803	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4804	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
4805	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4806	SWEDE	E	
4807	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

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			fragrance concentration in a medicine must be no more 1%.
4808	SWEET POTATO	E	
4809	SWERTIA CHIRATA	A, H	
4810	SWIETENIA MAHOGANI	A, H	
4811	SYAGRUS ROMANZOFFIANA	A, E, H	
4812	SYMPHYOTRICHUM NOVI-BELGII	A, H	
4813	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%.
4814	SYMPLOCARPUS FOETIDUS	A, H	
4815	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4816	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.
4817	SYNTHETIC WAX	E	
4818	SYRINGA RETICULATA	A, H	
4819	SYRINGA VULGARIS	A, H	
4820	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%.
4821	SYZYGIUM CUMINI	A, H	
4822	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%.
4823	TABEBUIA SERRATIFOLIA	A, E, H	
4824	TADEHAGI TRIQUETRUM	A, H	
4825	TAGETES ERECTA	A, E, H	When used as an excipient ingredient, only for use in combination with other permitted ingredients as a flavour

			proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
4826	TAGETES MINUTA	A, E, H	
4827	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%.
4828	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4829	TALLOW	E	Only for use in topical medicines for dermal application.
4830	TALLOW GLYCERIDES	E	
4831	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%.
4832	TAMARIX APHYLLA	A, H	
4833	TAMARIX CHINENSIS	A, H	
4834	TAMARIX GALLICA	A, H	
4835	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.
4836	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4837	TANACETUM COCCINEUM SUBSP. COCCINEUM	A, H	
4838	TANACETUM PARTHENIUM	A, E, H	
4839	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%.
4840	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%.
4841	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.
4842	TANNIC ACID	E	
4843	TAPIOCA STARCH	E	
4844	TARAXACUM MONGOLICUM	A, E, H	
4845	TARAXACUM OFFICINALE	A, E, H	

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4846	TARO	E	
4847	TARRAGON OIL	A, E, H	
4848	TARTARIC ACID	E	
4849	TARTRAZINE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4850	TARTRAZINE ALUMINIUM LAKE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4851	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%.
4852	TAURINE	A, E	
4853	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4854	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'.
4855	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.

4856	TERMINALIA CATAPPA	A, H	
4857	TERMINALIA CHEBULA	A, H	
4858	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%.
4859	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%.
4860	TERPENE RESIN	E	Terpene resin must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application.
4861	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

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4862	TERPINEOL	E	
4863	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%.
4864	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%.
4865	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%.

4866	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%.
4867	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%.
4868	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4869	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%.
4870	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%.
4871	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%.

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4872	TETRACLINIS ARTICULATA	A, E, H	
4873	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%.
4874	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.
4875	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%.
4876	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%.
4877	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%.
4878	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%.
4879	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%.
4880	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%.
4881	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%.
4882	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%.
4883	TETRAHYDROMUGUOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4884	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%.
4885	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4886	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%.
4887	TETRAPANAX PAPYRIFER	A, H	
4888	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4889	TETRASODIUM PYROPHOSPHATE	E	
4890	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4891	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.

4892	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4893	THAPSIA GARGANICA	A, H	
4894	THAUMATIN	E	
4895	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%.
4896	THEMEDA TRIANDRA	A, H	
4897	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma cacao. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. When the maximum

			recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines’ (or words to that effect).
4898	THEOBROMA OIL	A, E, H	
4899	THIAMINE	A, E	
4900	THIAMINE HYDROCHLORIDE	A, E	
4901	THIAMINE NITRATE	A, E	
4902	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%.
4903	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%.
4904	THLASPI ARVENSE	A, E, H	
4905	THREONINE	A, E	
4906	THUJA OCCIDENTALIS	A, H	
4907	THUJA PLICATA	A, E, H	
4908	THYME HERB DRY	A, E, H	
4909	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).
4910	THYMOL	A, E	When used as an active ingredient, the medicine must be medicated space spray or medicated throat lozenges. When used as an excipient, only for use in medicated throat lozenges or topical medicines for dermal applications.
4911	THYMOL METHYL ETHER	E	Thymol methyl ether must only be included in medicines when in combination with other permitted ingredients as a flavour

			proprietary excipient formulation. The total concentration of the flavour proprietary excipient formulation containing thymol methyl ether must not be more than 5% of the total medicine.
4912	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).
4913	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4914	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).
4915	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).
4916	THYMUS VULGARIS	A, E, H	When the plant preparation is oil or distillate, and the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4917	THYMUS VULGARIS MIS	A, E, H	When the plant preparation is an oil or distillate, and the concentration of Thymus vulgaris MIS oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4918	THYMUS ZYGIS	A, H	When the plant preparation is an oil or a distillate, and the concentration of Thymus zygis oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres;

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			(b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4919	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4920	TILACTASE	A	Must be derived from Aspergillus oryzae and comply with the relevant USP monograph.
4921	TILIA CORDATA	A, E, H	
4922	TILIA PLATYPHYLLOS	A, E, H	
4923	TILIA TOMENTOSA	A, H	
4924	TILIA X VULGARIS	A, E, H	
4925	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%.
4926	TIN	H	Only for use as an active homoeopathic ingredient.
4927	TINOSPORA CORDIFOLIA	A, H	
4928	TINOSPORA SINENSIS	A, H	
4929	TITANIUM DIOXIDE	A, E	For use as an active ingredient only in sunscreens for dermal application. The concentration in sunscreens must be no more than 25%. For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. Not to be included in medicines intended for use in the eye.

			When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4930	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%.
4931	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%
4932	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%.

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4933	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%
4934	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4935	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%.
4936	TOLU BALSAM	A, E, H	
4937	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%.
4938	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%.
4939	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%.
4940	TOMATO	E	
4941	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%.
4942	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%.
4943	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%.
4944	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4945	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.

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4946	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4947	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4948	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4949	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%.
4950	TRAGACANTH	A, E	
4951	TRAMETES VERSICOLOR	A, H	
4952	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4953	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%.

4954	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.
4955	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%.
4956	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%.
4957	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%.

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4958	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%.
4959	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%.
4960	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%.
4961	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%.
4962	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%.
4963	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%.
4964	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%.
4965	TRANS-2-OCTENAL	E	trans-2-Octenal must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing trans-2-octenal must not be more than 1% of the total medicine.
4966	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%.
4967	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%.
4968	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%.
4969	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%.
4970	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%.
4971	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%.
4972	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of treacle.

4973	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%.
4974	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.
4975	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.
4976	TREMELLA FUCIFORMIS	A, H	

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4977	TRIACETIN	E	
4978	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4979	TRIADICA SEBIFERA	A, H	
4980	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.
4981	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.
4982	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%.
4983	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%.
4984	TRIBULUS TERRESTRIS	A, E, H	

4985	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%.
4986	TRICALCIUM PHOSPHATE	E	
4987	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%.
4988	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%.
4989	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4990	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%.
4991	TRICHODERMA VIRIDE	A, E, H	
4992	TRICHOSANTHES KIRILOWII	A, E, H	
4993	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
4994	TRICYCLODECENYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4995	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%.
4996	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4997	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%.
4998	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%.
4999	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
5000	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%.

5001	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%.
5002	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
5003	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
5004	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%.
5005	TRIETHYL CITRATE	E	
5006	TRIETHYLENE GLYCOL	E	
5007	TRIFOLIUM PRATENSE	A, E, H	
5008	TRIFOLIUM REPENS	A, H	
5009	TRIGONELLA FOENUM-GRAECUM	A, E, H	
5010	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%.
5011	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
5012	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.

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5013	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%.
5014	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%.
5015	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
5016	TRILAURIN	E	Only for use in topical medicines for dermal application.
5017	TRILISA ODORATISSIMA	A, H	
5018	TRILLIUM ERECTUM	A, H	
5019	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%.
5020	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%.
5021	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%.
5022	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%.
5023	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%.
5024	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%.
5025	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5026	TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5027	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5028	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient. The total concentration of trinitrophenol in the medicine

			must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5029	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%.
5030	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%.
5031	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%.
5032	TRIOSTEUM PERFOLIATUM	A, H	
5033	TRIOXAUNDECANEDIOIC ACID	E	
5034	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%.
5035	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%.
5036	TRIS-BIPHENYL TRIAZINE	A	Only for use as an active

			ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used topically, the dosage form must not be spray. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
5037	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%.
5038	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
5039	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%.
5040	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%.

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5041	TRISTEARIN	E	
5042	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.
5043	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.
5044	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%.
5045	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5046	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
5047	TROLAMINE SALICYLATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 12%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when

			exposed to the sun' (or words to this effect).
5048	TROLLIUS CHINENSIS	A, H	
5049	TROMETAMOL	E	
5050	TROMETAMOL HYDROCHLORIDE	E	
5051	TROPAEOLUM MAJUS	A, E, H	
5052	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5053	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%.
5054	TSUGA CANADENSIS	A, H	
5055	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%.
5056	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5057	TURNERA DIFFUSA	A, E, H	Beta-arbutin is a mandatory component of Turnera diffusa. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory

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			component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5058	TURNIP	E	
5059	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than 25%.
5060	TYPHA ANGUSTIFOLIA	A, H	
5061	TYPHA LATIFOLIA	A, H	
5062	TYPHONIUM GIGANTEUM	A, H	
5063	TYROSINE	A, E	