

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
3635	P-ALPHA-DIMETHYL STYRENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3636	P-ANISIC ACID	E	<p>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.</p> <p>The concentration in the medicine must be no more than 0.3%.</p>
3637	PADIMATE O	A	<p>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.</p> <p>The concentration in the medicine must not be more than 8%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p>

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			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3638	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%.
3639	PAEONIA LACTIFLORA	A, E, H	
3640	PAEONIA OBOVATA	A, H	
3641	PAEONIA SUFFRUTICOSA	A, E, H	
3642	PAEONIA VEITCHII	A, H	
3643	PALIURUS SPINA-CHRISTI	A, H	
3644	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3645	PALM FRUIT OIL	A, E, H	
3646	PALM GLYCERIDES	E	
3647	PALM KERNEL OIL	A, E, H	
3648	PALM TOCOTRIENOLS COMPLEX	A, H	
3649	PALMARIA PALMATA	A, H	
3650	PALMAROSA OIL	A, E, H	
3651	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.'

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			- (ADULT) 'Adults only.' - (21DAYS) 'Not to be used for more than 21 consecutive days.'
3652	PALMITIC ACID	E	
3653	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3654	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%.
3655	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%
3656	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%.
3657	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%.
3658	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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3659	PANAX GINSENG	A, E, H	
3660	PANAX JAPONICUS	A, H	
3661	PANAX NOTOGINSENG	A, H	
3662	PANAX PSEUDOGINSENG	A, H	
3663	PANAX QUINQUEFOLIUS	A, H	
3664	PANICUM MILIACEUM	A, H	
3665	PANTETHINE	E	Only for use in topical medicines for dermal application.
3666	PANTHENOL	A, E	
3667	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3668	PANTOLACTONE	E	
3669	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3670	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%.
3671	PAPAIN	A, E	
3672	PAPER	E	Only for use in topical medicines for dermal application.
3673	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%.
3674	PARA-CRESOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3675	PARA-CRESYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3676	PARA-CRESYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3677	PARA-CRESYL PHENYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3678	PARA-CYMENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3679	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%.
3680	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.
3681	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%.
3682	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%.

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3683	PARA-HYDROXYBENZOIC ACID	E	
3684	PARA-MENTHA-8-THIOL-3-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3685	PARA-METHYL ACETOPHENONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3686	PARA-METHYL ANISOLE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3687	PARA-METHYL DIMETHYLBENZYL CARBINOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more 1%.
3688	PARA-PROPYL ANISOLE	E	<p>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.</p> <p>The total concentration of fragrance proprietary excipient formulations containing para-propyl anisole must not be more than 1% of the total medicine.</p> <p>The total concentration of flavour proprietary excipient formulations containing para-propyl anisole must not be more than 5% of the total medicine.</p>
3689	PARA-TERT-BUTYLCYCLOHEXYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3690	PARA-TERT-BUTYLPHENYL-ALPHA-METHYLHYDROCINNAMIC ALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3691	PARA-TOLUALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3692	PARA-TOLYL ACETALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3693	PARAMERIA LAEVIGATA	A, H	
3694	PARIETARIA JUDAICA	A, H	
3695	PARIS POLYPHYLLA	A, H	
3696	PARIS QUADRIFOLIA	A, H	
3697	PARSLEY HERB DRY	A, E, H	
3698	PARSLEY HERB OIL	A, E, H	
3699	PARSLEY HERB POWDER	A, E, H	
3700	PARSLEY SEED OIL	A, E, H	
3701	PARTHENOCISSUS TRICUSPIDATA	A, H	
3702	PARTIALLY DEHYDRATED LIQUID SORBITOL	E	<p>Sorbitol is a mandatory component of partially dehydrated liquid sorbitol.</p> <p>Permitted for use only as part of the capsule in medicines where the dosage form is a soft capsule.</p>
3703	PARTIALLY HYDROGENATED SOYA OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in the medicine must be no more than 5%.</p>
3704	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%.
3705	PASPALUM NOTATUM	A, H	
3706	PASSIFLORA CAERULEA	A, H	
3707	PASSIFLORA EDULIS	E	
3708	PASSIFLORA HERB DRY	A, H	
3709	PASSIFLORA INCARNATA	A, E, H	
3710	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%.
3711	PATENT BLUE V	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3712	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3713	PATRINIA SCABIOSIFOLIA	A, H	
3714	PATRINIA VILLOSA	A, H	
3715	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 medicine 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).
3716	PAULLINIA PINNATA	A, H	
3717	PAWPAW	E	
3718	PEA	E	
3719	PEA STARCH	E	
3720	PEACH	E	
3721	PEAR	E	
3722	PECAN	E	
3723	PECTIN	A, E	
3724	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%.
3725	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3726	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3727	PEG-12 DILAURATE	E	
3728	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%.

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3729	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3730	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3731	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3732	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3733	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%.
3734	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3735	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3736	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3737	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3738	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).
3739	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3740	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3741	PEG-35 CASTOR OIL	E	
3742	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3743	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%.
3744	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3745	PEG-40 CASTOR OIL	E	
3746	PEG-40 HYDROGENATED CASTOR OIL	E	
3747	PEG-40 SORBITAN DIISOSTEARATE	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of PEG-40

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			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%.
3748	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3749	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3750	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3751	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3752	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%.
3753	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3754	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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3755	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%.
3756	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3757	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3758	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3759	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3760	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3761	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%.
3762	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%.
3763	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

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			must be no more than 4%.
3764	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3765	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.
3766	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3767	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3768	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%.
3769	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%.
3770	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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3771	PELARGONIUM GRAVEOLENS	A, E, H	
3772	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%.
3773	PELTIGERA CANINA	A, H	
3774	PENICILLIUM EXPANSUM	A, H	
3775	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.
3776	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%
3777	PENTAERYTHRITYL	E	Only for use in topical medicines

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	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%.
3778	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3779	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%.
3780	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%.
3781	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%.
3782	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%.
3783	PEPPER BLACK	E, H	
3784	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%.
3785	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

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

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

			<p>concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3788	PEPPERMINT OIL	A, E, H	<p>Menthol is a mandatory component of peppermint oil.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(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:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(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:</p> <p>- (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p>

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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.
3789	PEPPERMINT OIL TERPENELESS E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more 1%.</p> <p>Menthol is a mandatory component of peppermint oil terpeneless.</p> <p>When the medicine is for topical use for dermal application:</p> <p>i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>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:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a</p>

			<p>large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>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:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3790	PEPPERMINT OIL TERPENES AND TERPENOIDS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>Menthol is a mandatory component of peppermint oil terpenes and terpenoids.</p> <p>When the medicine is for topical use for dermal application:</p> <p>i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>iv) if the medicine delivers more than 1% total menthol when</p>

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			<p>administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>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:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3791	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3792	PERHYDRO-3,6-DIMETHYLBENZO [B] FURAN-2-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3793	PERILLA FRUTESCENS	A, E, H	
3794	PERILLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3795	PERLITE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p>
3796	PERMETHRIN	E	<p>The total concentration of permethrin in the medicine must not be more than 2%.</p>
3797	PERSEA AMERICANA	A, E, H	
3798	PERSIC OIL	A, E, H	<p>Amygdalin and Hydrocyanic acid are mandatory components of Persic oil.</p> <p>The concentration of amygdalin in the medicine must be no more than 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
3799	PERSICARIA CHINENSIS	A, H	
3800	PERSICARIA TINCTORIA	A, H	
3801	PERU BALSAM	A, E, H	
3802	PERU BALSAM OIL	A, E, H	
3803	PETITGRAIN MANDARIN OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour</p> <p>The final concentration of the oil in the flavour does not exceed 30%</p> <p>If used in a flavour the total</p>

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			flavour concentration in a medicine must be no more than 5%
3804	PETITGRAIN OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3805	PETITGRAIN OIL CITRONNIER	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>When included in a medicine for use on the lips the concentration of petitgrain oil citronnier must be no more than 0.1%.</p> <p>When included in dermal creams for infant use the concentration of petitgrain oil citronnier must be no more than 0.5%</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
3806	PETITGRAIN OIL PARAGUAY	A, E, H	<p>When used internally, oxedrine is a mandatory component of petitgrain oil paraguay.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>
3807	PETITGRAIN OIL TERPENELESS	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%.
3808	PETROSELINUM CRISPUM	A, E, H	
3809	PEUCEDANUM PRAERUPTORUM	A, E, H	
3810	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).
3811	PHALARIS ARUNDINACEA	A, H	
3812	PHALARIS CANARIENSIS	A, H	
3813	PHASEOLUS COCCINEUS	A, H	
3814	PHASEOLUS VULGARIS	A, H	
3815	PELLINUS ROBINIAE	A, E, H	
3816	PHELLODENDRON AMURENSE	A, E, H	
3817	PHELLODENDRON CHINENSE	A, H	
3818	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3819	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%.
3820	PHENETHYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3821	PHENETHYL ALCOHOL	E	<p>Permitted for use only:</p> <p>a) in topical medicines for dermal application; and</p> <p>b) for internal use in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation concentration in a medicine must be no more than 5%.</p>
3822	PHENETHYL BENZOATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 6%.</p>
3823	PHENETHYL DIMETHICONE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.2%</p>
3824	PHENETHYL ISOAMYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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			If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3825	PHENETHYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3826	PHENETHYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3827	PHENETHYL PHENYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3828	PHENETHYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3829	PHENOL	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration of phenol in the medicine must be no more than 1%.</p>
3830	PHENOXYACETALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3831	PHENOXYETHANOL	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration of phenoxyethanol in the preparation must not exceed 15%.</p>
3832	PHENOXYETHYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3833	PHENOXYETHYLPARABEN	E	<p>Only for use in topical medicines for dermal application.</p>

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3834	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3835	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3836	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%.
3837	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%.
3838	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%.
3839	PHENYLACETIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3840	PHENYLALANINE	A, E	<p>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:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.</p>
3841	PHENYLBENZIMIDAZOLE SULFONIC ACID	A	<p>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.</p> <p>The concentration in the medicine must not be more than 4%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p>
3842	PHENYLETHYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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			5%.
3843	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%.
3844	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%.
3845	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%.
3846	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%.
3847	PHENYLETHYL METHYLETHYL	E	Permitted for use only in

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	CARBINOL		<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3848	PHENYLETHYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3849	PHENYLETHYL TIGLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3850	PHENYLISOPROPYL DIMETICONE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p>
3851	PHENYLPROPANOL	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.16%.</p>
3852	PHLEUM PRATENSE	A, H	

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3853	PHLOXINE B	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3854	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3855	PHOENIX DACTYLIFERA	A, E, H	
3856	PHOSPHATIDYL CHOLINE	E	
3857	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%.
3858	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3859	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%.
3860	PHOTINIA SERRULATA	A, H	
3861	PHRAGMITES AUSTRALIS	A, H	
3862	PHYLLANTHUS AMARUS	A, H	
3863	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
3864	PHYLLOSTACHYS NIGRA	A, E, H	
3865	PHYSALIS ALKEKENGI	A, H	
3866	PHYSALIS PUBESCENS	A, H	
3867	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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3868	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%.
3869	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3870	PHYTOMENADIONE	A, E	
3871	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%.
3872	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%.
3873	PICEA ABIES	A, H	
3874	PICEA MARIANA	A, H	
3875	PICRAMISMA EXCELSA	A, E, H	
3876	PICRORRHIZA KURROA	A, E, H	
3877	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%.
3878	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

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.21%.
3879	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%.
3880	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3881	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3882	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3883	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3884	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.
3885	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3886	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3887	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.

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3888	PILOCARPUS JABORANDI	A, H	<p>Pilocarpine is a mandatory component of Pilocarpus jaborandi.</p> <p>The concentration of pilocarpine in the medicine must be no more than 0.025%.</p>
3889	PILOCARPUS MICROPHYLLUS	A, H	<p>Pilocarpine is a mandatory component of Pilocarpus microphyllus.</p> <p>The concentration of pilocarpine in the medicine must be no more than 0.025%.</p>
3890	PILOCARPUS PINNATIFOLIUS	A, H	<p>Pilocarpine is a mandatory component of Pilocarpus pinnatifolius.</p> <p>The concentration of pilocarpine in the medicine must be no more than 0.025%.</p>
3891	PIMENTA FRUIT OIL	A, E, H	
3892	PIMENTA LEAF OIL	A, E, H	
3893	PIMENTA OFFICINALIS	A, E, H	
3894	PIMENTA RACEMOSA	A, E, H	<p>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.</p> <p>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.</p> <p>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</p>

			<p>no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'.
3895	PIMPINELLA ANISUM	A, E, H	<p>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%:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect).
3896	PIMPINELLA SAXIFRAGA	A, E, H	
3897	PINE NEEDLE OIL SCOTCH	A, E, H	
3898	PINE NEEDLE OIL TERPENELESS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3899	PINE OIL AROMATIC	A, E, H	

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3900	PINE OIL PUMILIO	A, E, H	
3901	PINEAPPLE	E	
3902	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%.
3903	PINELLIA TERNATA	A, H	
3904	PINUS CONTORTA	A, E, H	
3905	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%.
3906	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%.
3907	PINUS MONTICOLA	A, E, H	
3908	PINUS MUGO	A, E, H	
3909	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%.
3910	PINUS PINASTER	A, E, H	When the plant preparation is oil or distillate the total concentration

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			of Pinus pinaster oil or distillate in the preparation must be no more than 25%.
3911	PINUS PONDEROSA	A, E, H	
3912	PINUS RADIATA	A, E, H	
3913	PINUS STROBUS	A, E, H	
3914	PINUS SYLVESTRIS	A, E, H	
3915	PINUS TABULIFORMIS	A, E, H	
3916	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%.
3917	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%.
3918	PIPER CHABA	A, E, H	
3919	PIPER CUBEBA	A, E, H	
3920	PIPER KADSURA	A, E, H	
3921	PIPER LONGUM	A, E, H	
3922	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

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			<p>capsule then the quantity of kavalactones (of Piper methysticum) must be no more than 125 mg per tablet or capsule.</p> <p>Oral medicines containing more than 25 mg of kavalactones (of Piper methysticum) per dose require the following warning statement on the medicine label:</p> <p>- (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'.</p> <p>The plant part must be root or rhizome.</p> <p>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.</p> <p>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.</p> <p>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.</p>
3923	PIPER NIGRUM	A, E, H	
3924	PIPER SARMENTOSUM	A, E, H	
3925	PIPERINE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary formulation.</p> <p>The total flavour proprietary formulation in a medicine must not be more than 5% and the concentration of piperine in the</p>

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			medicine must not be more than 0.15%.
3926	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%.
3927	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%.
3928	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%.
3929	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application.
3930	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.
3931	PISCIDIA PISCIPULA	A, E, H	
3932	PISTACIA LENTISCUS	A, E, H	
3933	PISUM SATIVUM	A, E, H	
3934	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3935	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).
3936	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).
3937	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).
3938	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

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			statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3939	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).
3940	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).
3941	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).
3942	PLATANUS OCCIDENTALIS	A, E, H	
3943	PLATANUS RACEMOSA	A, H	
3944	PLATANUS × HISPANICA	A, H	
3945	PLATYCODON GRANDIFLORUS	A, E, H	
3946	PLECTRANTHUS BARBATUS	A, E, H	
3947	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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3948	PLUM	E	
3949	PLUMBAGO EUROPAEA	A, H	
3950	PLUMERIA ALBA	A, E, H	
3951	PLUMERIA RUBRA	A, E, H	
3952	POA NEMORALIS	A, H	
3953	POA PRATENSIS	A, H	
3954	PODOPHYLLUM PELTATUM	A, H	<p>Podophyllin and podophyllotoxin are mandatory components of Podophyllum peltatum.</p> <p>The concentration of podophyllin in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.</p> <p>The concentration of podophyllotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
3955	POGOSTEMON CABLIN	A, E, H	
3956	POLACRILIN	E	
3957	POLACRILIN POTASSIUM	E	
3958	POLAPREZINC	A	<p>Only for use in oral medicines.</p> <p>Zinc is a mandatory component of Polaprezinc.</p> <p>The maximum recommended daily dose must be no more than 34 milligrams of zinc sourced from polaprezinc.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which</p>

			may be dangerous if taken in large amounts or for a long period' (or words to that effect).
3959	POLIGLUSAM	A, E	<p>The average molecular mass of poliglusam must be greater than 2 kilodaltons.</p> <p>When for internal use:</p> <p>(a) the maximum recommended daily dose of the medicine must not provide more than 1750 milligrams poliglusam; and</p> <p>(b) the following warning statement is required on the medicine label:</p> <p>- (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).</p> <p>When for internal use and the dosage form is a powdered preparation, the following warning statement is required on the medicine label:</p> <p>- (DNTPOW) 'Do not take powder alone. Mix with food or fluid'.</p> <p>When used as an excipient, only for use in topical medicines for dermal application.</p>
3960	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	<p>When for oral use:</p> <p>(a) the maximum recommended daily dose of the medicine must not provide more than 2000 mg of Poliglusam derived from Aspergillus niger;</p> <p>(b) the following warning statement (or words to the same effect) is required on the medicine label:</p> <p>- (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce</p>

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			<p>the effect of other medication.';</p> <p>and</p> <p>(c) if the medicine is a powdered dosage form, the following warning statement is also required on the medicine label:</p> <p>- (DNTPOW) 'Do not take powder alone. Mix with food or fluid.'</p> <p>When used as an excipient, Poliglusam derived from <i>Aspergillus niger</i> is only permitted for use in topical medicines for dermal application.</p>
3961	POLLACK-LIVER OIL	A, E	<p>Colecalciferol and Vitamin A are mandatory components of Pollack-liver oil.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>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:</p> <p>- (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.</p> <p>- (VITA4) 'WARNING - When taken in excess of 3000</p>

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			<p>micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (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.'</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p>
3962	POLLEN	E	<p>The medicine requires the following warning statement on the medicine label:</p> <p>- (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect).</p>
3963	POLOXAMER	E	<p>Only for use in topical medicines for dermal application.</p>
3964	POLOXAMINE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3965	POLY C10-30 ALKYL ACRYLATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p>
3966	POLYACRYLAMIDE	E	<p>Only for use in topical medicines for dermal application.</p>

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			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

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			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%
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

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			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%.

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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. 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

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			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/DIME R DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4003	POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROX	E	Only for use in topical medicines for dermal application and not to

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	YSTEARATE/SEBACATE		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. 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

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			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	POLYMETHYLSILSESQUIOXAN E	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 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 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

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			for dermal 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%.

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4036	POLYSILICONE-15	A	<p>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.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (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	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.13%.</p>
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

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			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 <i>Poncirus trifoliata</i> . The quantity of Oxedrine in the maximum recommended daily dose must be no more than 30 mg.

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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

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			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,

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			<p>the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
4081	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4082	POTASSIUM CHLORIDE	A, E, H	<p>When for oral use:</p> <p>(a) potassium is a mandatory component of potassium chloride;</p> <p>(b) the medicine requires the following warning statement on the medicine label:</p> <p>- (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</p> <p>(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.</p> <p>Medicines containing potassium chloride for use as oral rehydration therapy, are subject to the following conditions:</p> <p>(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;</p> <p>(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</p>

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			<p>United Nations Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and</p> <p>(c) the following warning statements are required on the medicine label:</p> <p>- (UOAD) 'Use only as directed'</p> <p>- (DIAR3) 'If diarrhoea persists, seek medical advice.'</p> <p>When for dental use, the concentration of potassium chloride in the medicine must not be more than 3.75%.</p>
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	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 10%.</p>
4085	POTASSIUM COCOYL HYDROLYSED SOY PROTEIN	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.15%.</p>
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

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			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. 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

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			<p>dose of the medicine must contain less than 300 micrograms of iodine.</p> <p>When for external use, the concentration of iodine in the medicine (excluding salts derivatives or iodophors) must not exceed 2.5%.</p>
4093	POTASSIUM METABISULFITE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4094	POTASSIUM METAPHOSPHATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
4095	POTASSIUM NITRATE	A, H	<p>Only for dental use.</p> <p>The concentration in the medicine must be no more than 5%.</p>
4096	POTASSIUM OROTATE	A, E, H	<p>When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium orotate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
4097	POTASSIUM PYROPHOSPHATE	E	<p>Only for oral application, dental or topical use.</p>

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			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	
4108	POTERIUM OFFICINALE	A, E, H	
4109	POTERIUM SANGUISORBA	A, H	
4110	POVIDONE	E	
4111	POWDERED CELLULOSE	E	

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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

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			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 fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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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

				<p>- in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The concentration of propan-1-ol in the medicine must not be more than 18%.</p> <p>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%.</p>
4142	PROPANE	E		Only for use as an excipient propellant ingredient.
4143	PROPANEDIOL	E		<p>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.</p> <p>The concentration in the medicine must be no more than 10%.</p>
4144	PROPENYL GUAETHOL	E		<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4145	PROPIONALDEHYDE	E		<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a</p>

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4146	PROPIONIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4147	PROPIONYLLEVO-CARNITINE HYDROCHLORIDE	A, H	
4148	PROPOLIS	A, E	<p>Lead is a mandatory component of Propolis.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>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.'</p>
4149	PROPOLIS BALSAM	A, E	<p>Lead is a mandatory component of Propolis balsam.</p> <p>The concentration of lead in the medicine must be no more than</p>

			<p>0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4150	PROPOLIS DRY EXTRACT	A, E	<p>Lead is a mandatory component of Propolis dry extract.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4151	PROPOLIS LIQUID EXTRACT	A, E	<p>Lead is a mandatory component of Propolis liquid extract.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p>

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			<p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4152	PROPOLIS RESIN	A, E	<p>Lead is a mandatory component of propolis resin.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4153	PROPOLIS TINCTURE	A, E	<p>Lead is a mandatory component of Propolis tincture.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for</p>

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			<p>topical, the medicine requires the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4154	PROPYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4155	PROPYL CAPROATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
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	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4161	PROPYLENE GLYCOL DIBENZOATE	E	Only for use in topical medicines for dermal application only and

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			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 <i>Aspergillus</i>

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			oryzae or <i>Aspergillus niger</i> .
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 <i>Prunus africana</i> . 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 <i>Prunus armeniaca</i> 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

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			<p>are mandatory components of <i>Prunus avium</i>.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4180	PRUNUS CERASIFERA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus cerasifera</i>.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4181	PRUNUS CERASUS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus cerasus</i>.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4182	PRUNUS DOMESTICA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus domestica</i>.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4183	PRUNUS DULCIS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus dulcis</i> when the plant part is seed.</p>

			<p>When the plant part is seed, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry seed.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4184	PRUNUS HUMILIS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus humilis.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4185	PRUNUS JAPONICA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus japonica.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4186	PRUNUS LAUROCERASUS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4187	PRUNUS MUME	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of</p>

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			<p>Prunus mume.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4188	PRUNUS PERSICA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus persica.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4189	PRUNUS SALICINA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4190	PRUNUS SEROTINA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus serotina.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4191	PRUNUS SPINOSA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p>

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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%.
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 required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4202	PTELEA TRIFOLIATA	A, H	

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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	<p>Pyridoxine is a mandatory component of pyridoxal 5-phosphate.</p> <p>The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <ul style="list-style-type: none"> (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. <p>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:</p> <p>- (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].</p>
4223	PYRIDOXAL 5-PHOSPHATE	A	Pyridoxine is a mandatory

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	<p>MONOHYDRATE</p>	<p>component of pyridoxal 5-phosphate monohydrate.</p> <p>The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <ul style="list-style-type: none"> (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. <p>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:</p> <p>- (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].'</p>
<p>4224</p>	<p>PYRIDOXINE HYDROCHLORIDE A, E, H</p>	<p>When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of pyridoxine hydrochloride.</p> <p>The percentage of pyridoxine</p>

			<p>from pyridoxine hydrochloride should be calculated based on the molecular weight of pyridoxine hydrochloride.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive);</p> <p>(ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive);</p> <p>(iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive);</p> <p>(iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and</p> <p>(v) 100 mg of pyridoxine for individuals aged 19 years and older.</p> <p>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:</p> <p>- (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].'</p>
4225	PYROGLUTAMIC ACID	E	
4226	PYROLA DECORATA	A, H	
4227	PYROLIGNEOUS ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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			5%.
4228	PYRROSIA LINGUA	A, H	
4229	PYRROSIA PETIOLOSA	A, H	
4230	PYRROSIA SHEARERI	A, H	
4231	PYRUS COMMUNIS	A, E, H	<p>Beta-arbutin is a mandatory component of <i>Pyrus communis</i>.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>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%.</p>
4232	PYRUS PYRIFOLIA	A, H	<p>Beta-arbutin is a mandatory component of <i>Pyrus pyrifolia</i>.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of</p>

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			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 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

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			<p>application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</p> <p>Not be used in medicines in which N-nitroso compounds may be formed.</p>
4242	QUATERNIUM-80	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2.5%.</p>
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	QUILLAIA SAPONARIA	A, H	
4254	QUINCE	E	
4255	QUININE ARSENITE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>Quinine is a mandatory component of Quinine arsenite.</p> <p>The maximum recommended daily dose must be no more than 50 mg of quinine.</p>
4256	QUININE SULFATE DIHYDRATE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>Quinine is a mandatory component of quinine sulfate dihydrate.</p>

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			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%. 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

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			<p>the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>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:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>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:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4263	RADISH	E	
4264	RAISIN JUICE CONCENTRATE	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%.
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%.
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

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			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	

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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	REFINED BUGLOSSOIDES ARVENSIS SEED OIL	A	<p>Only to be used in a medicine where Phytolove Pty Ltd (Client ID 80651), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 3 July 2025.</p> <p>Stearidonic acid is a mandatory component of refined Buglossoides arvensis seed oil.</p> <p>The route of administration for medicines that contain refined Buglossoides arvensis seed oil must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 500 mg of stearidonic acid.</p> <p>The following warning statement (or words to that effect) is required on the medicine label:</p> <p>- (NTAKEN3) 'Not to be taken by children under 3 years old'.</p>

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4289	REHMANNIA GLUTINOSA	A, E, H	
4290	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%.
4291	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%.
4292	RESORCINOL DIMETHYLETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4293	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'.
4294	RETINOL	A, E	<p>Vitamin A is a mandatory component of retinol.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>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:</p> <p>- (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.</p> <p>- (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.</p> <p>- (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.'</p>

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4295	RETINOL ACETATE	A, E	<p>Vitamin A is a mandatory component of retinol acetate.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>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:</p> <ul style="list-style-type: none"> - (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	RETINOL PALMITATE	A, E	<p>Vitamin A is a mandatory component of retinol palmitate.</p> <p>When for use in topical medicines,</p>

			<p>the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>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:</p> <p>- (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.</p> <p>- (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.</p> <p>- (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.’</p>
4297	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4298	RHAMNOSE	E	Permitted for use only in combination with other permitted

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			<p>ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4299	RHAMNUS CATHARTICA	A, H	<p>When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica.</p> <p>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:</p> <ul style="list-style-type: none"> - (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). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'.

			<p>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:</p> <ul style="list-style-type: none"> - (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'.
4300	RHAMNUS FRANGULA	A, H	<p>Glucofrangulins calculated as glucofrangulin A is a mandatory component of Rhamnus frangula.</p> <p>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:</p> <ul style="list-style-type: none"> - (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). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect).

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			<p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <p>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:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4301	RHATANY ROOT DRY	A, H	
4302	RHATANY ROOT POWDER	A, H	
4303	RHEUM OFFICINALE	A, E, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum officinale.</p> <p>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:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and

			<p>- (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).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect).</p> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4304	RHEUM PALMATUM	A, E, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum palmatum.</p>

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
-

			<p>under 12 years is not recommended’;</p> <ul style="list-style-type: none"> - (LAX1) ‘Drink plenty of water’ (or words to that effect); and - (LAX2) ‘Prolonged use may cause serious bowel problems’.
4305	RHEUM RHAPONTICUM	A, E, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rheum rhaponticum.</p> <p>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:</p> <ul style="list-style-type: none"> - (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). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) ‘Drink plenty of water’ (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) ‘This product contains

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			<p>[name of the herb(s) or the chemical component(s)]; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4306	RHEUM TANGUTICUM	A, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum tanguticum.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (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).</p>

			<p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <p>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:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4307	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4308	RHODINOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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4309	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%.
4310	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.
4311	RHODODENDRON AUREUM	A, H	
4312	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%.

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4313	RHODODENDRON GROENLANDICUM	A, H	
4314	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4315	RHUBARB	E, H	<p>When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhubarb.</p> <p>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:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; <p>and</p> <ul style="list-style-type: none"> - (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). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and

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			<p>- (LAX4) 'This product may have laxative effect'.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4316	RHUBARB ROOT DRY	A, H	<p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of rhubarb root dry.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (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).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on</p>

			<p>the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <p>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:</p> <ul style="list-style-type: none"> - (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	RHUBARB ROOT POWDER	A, H	<p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of rhubarb root powder.</p> <p>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:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; <p>and</p>

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- (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'.

4318	RHUS AROMATICA	A, E, H	
4319	RHUS CHINENSIS	A, H	
4320	RHUS GLABRA	A, E, H	
4321	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.

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4322	RIBES GROSSULARIA	A, E, H	
4323	RIBES NIGRUM	A, E, H	
4324	RIBOFLAVIN	A, E	
4325	RIBOFLAVIN SODIUM PHOSPHATE	A, E	
4326	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4327	RIBOFLAVINE	A, E	
4328	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4329	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4330	RIBOSE	A	Only for use in oral medicines.
4331	RICE	E	
4332	RICE BRAN	E	
4333	RICE BRAN OIL	E	
4334	RICE BRAN WAX	A, E, H	
4335	RICE STARCH	E	
4336	RICE VINEGAR	E	
4337	RICE WINE	E	Ethanol is a mandatory component of rice wine.
4338	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4339	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4340	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.
4341	ROHDEA JAPONICA	A, H	The maximum recommended

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			daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4342	ROSA ARVENSIS	A, E, H	
4343	ROSA CANINA	A, E, H	
4344	ROSA CYMOSA	A, E, H	
4345	ROSA EGLANTERIA	A, E, H	
4346	ROSA GALLICA	A, E, H	
4347	ROSA LAEVIGATA	A, E, H	
4348	ROSA MULTIFLORA	A, E, H	
4349	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%.
4350	ROSA RUGOSA	A, E, H	
4351	ROSA VILLOSA	A, E, H	
4352	ROSA X CENTIFOLIA	A, E, H	
4353	ROSA X DAMASCENA	A, E, H	
4354	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%.
4355	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%.

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4356	ROSE FRUIT FRESH	A, E, H	
4357	ROSE HIP	E	
4358	ROSE OIL	A, E, H	
4359	ROSE OXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4360	ROSEMARY OIL	A, E, H	<p>Safrole is a mandatory component of Rosemary oil.</p> <p>When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.</p> <p>When for topical use then the concentration of safrole in the medicine must be no more than 1%.</p>
4361	ROSMARINUS OFFICINALIS	A, E, H	<p>Camphor and cineole are mandatory components of Rosmarinus officinalis.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p> <p>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.</p> <p>In liquid preparations other than</p>

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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.

4362	ROYAL JELLY	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by
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			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 FRESH	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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	ROYAL JELLY LYOPHILISED	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly lyophilised.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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'.
4365	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.

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4366	RUBIA CORDIFOLIA	A, H	
4367	RUBIA TINCTORUM	A, H	
4368	RUBUS CHINGII	A, H	
4369	RUBUS CORCHORIFOLIUS	A, H	
4370	RUBUS COREANUS	A, E, H	
4371	RUBUS FRUTICOSUS	A, E, H	
4372	RUBUS IDAEUS	A, E, H	
4373	RUBUS OCCIDENTALIS	A, E, H	
4374	RUBUS PARVIFOLIUS	A, H	
4375	RUBUS ROSIFOLIUS	A, H	
4376	RUDBECKIA HIRTA	A, H	
4377	RUE OIL	A, H	
4378	RUM	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4379	RUMEX ACETOSA	A, H	
4380	RUMEX ACETOSELLA	A, H	
4381	RUMEX CONGLOMERATUS	A, H	
4382	RUMEX CRISPUS	A, E, H	
4383	RUMEX PULCHER	A, H	
4384	RUMEX SCUTATUS	A, H	
4385	RUSCUS ACULEATUS	A, H	
4386	RUTA GRAVEOLENS	A, E, H	
4387	RUTOSIDE	A, E	
4388	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4389	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.

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4390	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%.
4391	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.
4392	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%.
4393	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%.
4394	SACCHARIN	E	
4395	SACCHARIN SODIUM	E	
4396	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4397	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	

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4398	SACCHAROMYCES CEREVISIAE POLYSACCHARIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4399	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4400	SACCHARUM OFFICINARUM	A, E, H	
4401	SAFFLOWER OIL	A, E, H	
4402	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4403	SAGE LEAF DRY	A, E, H	Thujone is a mandatory component of Sage leaf dry. The concentration of thujone in the medicine must be no more than 4%.
4404	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%.
4405	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:

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			- (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
4406	SAGE OIL SPANISH	A, E, H	
4407	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%.
4408	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%.
4409	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4410	SALIX ALBA	A, E, H	
4411	SALIX DAPHNOIDES	A, H	
4412	SALIX DISCOLOR	A, H	
4413	SALIX FRAGILIS	A, H	
4414	SALIX NIGRA	A, H	
4415	SALIX PURPUREA	A, H	
4416	SALSOLA KALI	A, H	
4417	SALVIA CHINENSIS	A, H	
4418	SALVIA FRUTICOSA	A, H	
4419	SALVIA HISPANICA	A, E, H	
4420	SALVIA LAVANDULAEFOLIA	A, H	
4421	SALVIA MILTIORRHIZA	A, H	

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4422	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%.
4423	SALVIA SCLAREA	A, E, H	
4424	SAMBUCUS CANADENSIS	A, H	
4425	SAMBUCUS EBULUS	A, H	
4426	SAMBUCUS NIGRA	A, E, H	
4427	SANDALWOOD OIL EAST INDIAN	A, E, H	
4428	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4429	SANICULA EUROPAEA	A, H	
4430	SANTALUM ALBUM	A, E, H	
4431	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.
4432	SAPINDUS MUKOROSI	A, H	
4433	SAPONARIA OFFICINALIS	A, H	
4434	SAPOSHNIKOVIA DIVARICATA	A, H	
4435	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%.
4436	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%

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			or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
4437	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.
4438	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%.
4439	SATUREIA HORTENSIS	A, H	
4440	SATUREIA MONTANA	A, H	
4441	SAUROPUS SPATULIFOLIUS	A, H	
4442	SAURURUS CHINENSIS	A, H	
4443	SAUSSUREA COSTUS	A, H	
4444	SAVORY OIL SUMMER	A, H	
4445	SAXIFRAGA GRANULATA	A, E, H	
4446	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.

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			The concentration in the medicine must not be more than 0.0816%.
4447	SCAPHIUM SCAPHIGERUM	A, H	
4448	SCHEFFLERA HEPTAPHYLLA	A, H	
4449	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4450	SCHINUS MOLLE	A, H	
4451	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%.
4452	SCHISANDRA CHINENSIS	A, E, H	
4453	SCHIZONEPETA TENUIFOLIA	A, E, H	
4454	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%.
4455	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%.
4456	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

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1%.			
4457	SCLERANTHUS ANNUUS	A, H	
4458	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4459	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%.
4460	SCROPHULARIA NINGPOENSIS	A, H	
4461	SCROPHULARIA NODOSA	A, H	
4462	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4463	SCUTELLARIA BAICALENSIS	A, E, H	
4464	SCUTELLARIA BARBATA	A, H	
4465	SCUTELLARIA LATERIFLORA	A, E, H	
4466	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%.
4467	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%.
4468	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%.
4469	SECALE CEREALE	A, H	Gluten is a mandatory component

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			of Secale cereale when the plant part is seed and the route of administration is other than topical and mucosal.
4470	SEDUM ACRE	A, H	
4471	SELAGINELLA TAMARISCINA	A, H	
4472	SELENICEREUS GRANDIFLORUS	A, E, H	
4473	SELENIUM	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>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.</p> <p>A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'</p>
4474	SELENOCYSTEINE	A	<p>Selenium is a mandatory component of Selenocysteine for oral and sublingual use.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>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.</p> <p>A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.'</p>

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4475	SELENOMETHIONINE	A	<p>Selenium is a mandatory component of Selenomethionine for oral and sublingual use.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (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.'</p>
4476	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4477	SEMECARPUS ANACARDIUM	A, H	<p>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.</p>
4478	SEMOLINA	E	
4479	SEMPERVIVUM TECTORUM	A, H	
4480	SENEGA ROOT DRY	A, H	
4481	SENEGA ROOT POWDER	A, H	
4482	SENNA ALEXANDRINA	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna alexandrina.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p>

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- (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 DRY	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a
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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:

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- (CHILD3) 'Use in children under 12 years is not recommended';
- (LAX1) 'Drink plenty of water' (or words to that effect); and
- (LAX2) 'Prolonged use may cause serious bowel problems'.

4484	SENNA FRUIT ALEXANDRIAN POWDER	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian powder.</p> <p>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:</p> <ul style="list-style-type: none">- (CHILD3) 'Use in children under 12 years is not recommended';- (LAX2) 'Prolonged use may cause serious bowel problems'; <p>and</p> <ul style="list-style-type: none">- (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). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none">- (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none">- (LAX5) 'This product contains [name of the herb(s) or the
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			<p>chemical component(s)']; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4485	SENNA FRUIT TINNEVELLY DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly dry.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (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).</p> <p>When promoted or marketed as a</p>

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			<p>laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <p>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:</p> <ul style="list-style-type: none"> - (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 FRUIT TINNEVELLY POWDER	A, H	<p>When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly powder.</p> <p>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:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may

			<p>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'.</p>
4487	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

			<p>12 years is not recommended';</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4488	SENNA LEAF POWDER	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Leaf Powder.</p> <p>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:</p> <ul style="list-style-type: none"> - (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). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and

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			<p>- (LAX4) 'This product may have laxative effect'.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4489	SENNA OCCIDENTALIS	A, H	<p>Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna occidentalis when the route of administration is oral administration.</p> <p>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:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (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].</p> <p>When promoted or marketed as a laxative, the medicine requires the</p>

			<p>following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' [or words to that effect]. <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <p>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:</p> <ul style="list-style-type: none"> - (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	SENNA TORA	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna tora.</p> <p>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:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems';

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			<p>and</p> <ul style="list-style-type: none"> - (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). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <p>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:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4491	SEPIA	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (MOLLUSC) 'Contains mollusc'

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				or 'Contains mollusc products'.
4492	SEQUOIA SEMPERVIRENS	A, H		
4493	SEQUOIADENDRON GIGANTEUM	A, H		
4494	SERENOA REPENS	A, H		
4495	SERINE	A, E		
4496	SERUM ANGUILLAE	H		Only for use as an active homoeopathic ingredient.
4497	SESAME OIL	A, E, H		
4498	SESAMUM INDICUM	A, E, H		
4499	SETARIA ITALICA	A, H		
4500	SHARK CALCIUM CHONDROITIN SULFATE	A		
4501	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)
4502	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%.
4503	SHARK POTASSIUM CHONDROITIN SULFATE	A		
4504	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

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			- the concentration in the medicine must be no more than 0.001%.
4505	SHARK-LIVER OIL	A, E	<p>Vitamin A and Colecalciferol are mandatory components of Shark-liver oil.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>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:</p> <ul style="list-style-type: none"> - (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

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			all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’
4506	SHEA BUTTER	E	
4507	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%.
4508	SHEA BUTTER UNSAAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4509	SHELLAC	E	
4510	SHEPHERD'S PURSE HERB DRY	A, H	
4511	SHEPHERD'S PURSE HERB POWDER	A, H	
4512	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%.
4513	SIGESBECKIA ORIENTALIS	A, E, H	
4514	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%.

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4515	SILICA DIMETHYL SILYLATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 4%.</p>
4516	SILICA SILYLATE	E	<p>Only for use in topical medicines for dermal application.</p>
4517	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	<p>Only for use when the route of administration is other than inhalation.</p>
4518	SILICON DIOXIDE	A, E, H	<p>Only for use when the route of administration is other than inhalation.</p>
4519	SILICONE QUATERNIUM-8	E	<p>Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2.5%.</p> <p>The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect).</p>
4520	SILVER	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>When for external use, the total concentration of silver in the medicine must not be more than 1%.</p> <p>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</p>

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			statement is required on the medicine label: - 'Overuse may stain skin or mouth.' (or words to that effect).
4521	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%.
4522	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4523	SILYBUM MARIANUM	A, E, H	
4524	SIMABA CEDRON	A, H	
4525	SIMETHICONE	E	
4526	SIMMONDSIA CHINENSIS	A, E, H	
4527	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%.
4528	SINAPIS ARVENSIS	A, H	
4529	SINOMENIUM ACUTUM	A, H	
4530	SIPHONESTEGIA CHINENSIS	A, H	
4531	SIRAITIA GROSVENORII	A, E, H	
4532	SISYMBRIUM OFFICINALE	A, H	
4533	SKATOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4534	SKIPJACK-LIVER OIL	A, E	<p>Vitamin A and Colecalciferol are mandatory components of Skipjack-liver oil.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>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:</p> <p>- (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.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents -</p>

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			<p>vitamin A can cause birth defects.’</p> <p>NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (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.’</p>
4535	SLIPPERY ELM BARK DRY	A, H	
4536	SLIPPERY ELM BARK POWDER	A, E, H	
4537	SMILAX ARISTOLOCHIIFOLIA	A, H	
4538	SMILAX CHINA	A, H	
4539	SMILAX GLABRA	A, H	
4540	SMILAX OFFICINALIS	A, E, H	
4541	SMILAX ORNATA	A, E, H	
4542	SMOKE EXTRACT	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4543	SODIUM ACETATE	E	
4544	SODIUM ACETYLATED HYALURONATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</p>
4545	SODIUM ACID CITRATE	A, E, H	<p>When sodium acid citrate is used as an active ingredient, only for use in oral medicines.</p>
4546	SODIUM ACRYLATES COPOLYMER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p>

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			The concentration in the medicine must be no more than 0.8%.
4547	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).
4548	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).
4549	SODIUM ALGINATE	E	
4550	SODIUM ASCORBATE	A, E, H	
4551	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%.
4552	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%.
4553	SODIUM BENZOATE	E	
4554	SODIUM BETA-HYDROXY-	A, H	

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BETA-METHYLBUTYRATE			
4555	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4556	SODIUM BICARBONATE	A, E	<p>When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms.</p> <p>Medicines containing sodium bicarbonate for use as oral rehydration therapy are subject to the following conditions:</p> <p>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;</p> <p>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.'</p> <p>c) the following warning statements are required on the medicine label:</p> <p>- (UOAD) 'Use only as directed.'</p> <p>- (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).'</p> <p>- (DIAR3) 'If diarrhoea persists, seek medical advice.'</p>
4557	SODIUM BISULFITE	E	

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4558	SODIUM BROMIDE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>The total concentration of sodium bromide in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
4559	SODIUM BUTYRATE	A, E	<p>The route of administration for medicines that contain sodium butyrate must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 1200 mg sodium butyrate.</p> <p>The following warning statement (or words to the same effect) is required on the medicine label: - (ADULT) 'Adults only'.</p>
4560	SODIUM C14-16 OLEFIN SULFONATE	E	<p>Only for use in topical medicines for dermal application.</p>
4561	SODIUM CALCIUM EDETATE	E	<p>When for oral use, sodium is a mandatory component of sodium calcium edetate.</p> <p>Sodium calcium edetate must only be included in medicines when:</p> <p>(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.</p> <p>The total concentration of sodium calcium edetate in the medicine must not exceed 0.32%.</p> <p>The total concentration of flavour proprietary excipient formulations containing sodium calcium edetate must not be more than 5% of the total medicine.</p>
4562	SODIUM CARBOMER	E	<p>Only for use as an excipient in</p>

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			topical medicines for dermal application.
4563	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.
4564	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.
4565	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%.
4566	SODIUM CARRAGEENAN	E	
4567	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%.
4568	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4569	SODIUM CHLORIDE	A, E, H	

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4570	SODIUM CHONDROITIN SULFATE	A, E	<p>When used as an excipient ingredient:</p> <p>a) only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye;</p> <p>b) the concentration in the medicine must not be more than 0.001%.</p> <p>When used as an active ingredient:</p> <p>a) the route of administration must only be oral;</p> <p>b) the maximum daily dose must not provide more than 1,200 mg of sodium chondroitin sulfate;</p> <p>c) the following statements must be included on the medicine label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect); - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
4571	SODIUM CITRATE	A, E	When for use as an active ingredient, only for oral use.
4572	SODIUM CITRATE DIHYDRATE	A, E	When for use as an active ingredient, only for oral use.
4573	SODIUM COCO PG-DIMONIUM CHLORIDE PHOSPHATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.05%.</p>
4574	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4575	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.

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4576	SODIUM CYCLAMATE	E	
4577	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4578	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%.
4579	SODIUM DODECYLBENZENESULFONAT E	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4580	SODIUM ERYTHORBATE	E	
4581	SODIUM ETHYL HYDROXYBENZOATE	E	
4582	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.'

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- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'

4583	SODIUM FUMARATE	E	
4584	SODIUM HYALURONATE	A, E	<p>When for use as an excipient ingredient, sodium hyaluronate must only be used in medicines with a topical route of administration for dermal application.</p> <p>When for use as an active ingredient:</p> <p>(a) the molecular mass of sodium hyaluronate must be between 600 and 1600 kilodaltons; and</p> <p>(b) sodium hyaluronate must only be used in medicines when the route of administration is limited to:</p> <p>(i) topical for dermal application; or</p> <p>(ii) oral.</p> <p>When for use in a topical medicine for dermal application the concentration of sodium hyaluronate in the medicine must not exceed 2.0%.</p> <p>When for use as an active ingredient and the route of administration is oral:</p> <p>(a) the maximum recommended daily dose must not provide more than 200 milligrams sodium hyaluronate;</p> <p>(b) the recommended duration of use of the medicine must be limited to three months; and</p> <p>(c) the following warning statements (or words to the same effect) are required on the medicine label :</p> <p>- (ADULT) 'Adults only'; and</p> <p>- (PREGNT) ' Not recommended</p>

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			for use by pregnant and lactating women'.
4585	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4586	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.
4587	SODIUM HYDROXYCITRATE	A	
4588	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%.
4589	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4590	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of sodium hypochlorite. The concentration of chlorine in the medicine must not be more than 4%.
4591	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4592	SODIUM LACTATE	E	
4593	SODIUM LAURETH SULFATE	E	
4594	SODIUM LAUROAMPHOACETATE	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4595	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%.
4596	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4597	SODIUM LAURYL PHOSPHATE	E	
4598	SODIUM LAURYL SULFATE	E	
4599	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4600	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4601	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%.
4602	SODIUM METABISULFITE	E	
4603	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%.
4604	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine

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			must be no more than 2%.
4605	SODIUM METHYL HYDROXYBENZOATE	E	
4606	SODIUM MOLYBDATE DIHYDRATE	A	<p>Only for use in oral medicines.</p> <p>Molybdenum is a mandatory component of Sodium molybdate dihydrate.</p> <p>The percentage of molybdenum from sodium molybdate dihydrate should be calculated based on the molecular weight of sodium molybdate dihydrate.</p> <p>The maximum daily dose of molybdenum from Sodium molybdate dihydrate must be no more than 125 micrograms.</p>
4607	SODIUM MONOFLUOROPHOSPHATE	A	<p>Fluoride is a mandatory component of sodium monofluorophosphate.</p> <p>The route of administration must be limited to dental.</p> <p>The dosage form must be limited to pastes, powders and/or gels for dental hygiene.</p> <p>When sodium monofluorophosphate is used as an active ingredient, it is subject to the following conditions:</p> <p>(a) only for use in combination with at least one other active ingredient; and</p> <p>(b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg.</p> <p>When the concentration of fluoride ion is more than 1000 mg/kg, the following warning statements are required on the medicine label:</p> <p>- (DNTSW) 'Do not swallow.'</p> <p>- (CHILD4) 'Do not use [this</p>

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			product/insert name of product] in children 6 years of age or less.'
4608	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%.
4609	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4610	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4611	SODIUM PANTOTHENATE	A, E, H	
4612	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4613	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

			<p>- (ADULT) 'Adults only' (or words to that effect).</p> <p>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:</p> <p>- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or</p> <p>- (ADULT) 'Adults only' (or words to that effect).</p> <p>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:</p> <p>- (BORON) 'Contains boron' (or words to that effect).</p> <p>When the medicine is for topical use for dermal application, the following warning statement is required on the label:</p> <p>- (BROKEN) 'Use on unbroken skin only' (or words to that effect).</p>
4614	SODIUM PERCARBONATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 15%.</p>
4615	SODIUM POLYACRYLATE	E	<p>Only for use in topical medicines for dermal application.</p>
4616	SODIUM POLYACRYLATE STARCH	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended</p>

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			for use in the eye. The concentration in the medicine must not be more than 1%.
4617	SODIUM POLYMETAPHOSPHATE	E	
4618	SODIUM PROPIONATE	E	
4619	SODIUM PROPYL HYDROXYBENZOATE	E	
4620	SODIUM RNA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
4621	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.'
4622	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

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			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	A, H	<p>Selenium is a mandatory component of Sodium selenite.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (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.'</p>
4624	SODIUM SELENITE PENTAHYDRATE	A	<p>Selenium is a mandatory component of Sodium selenite pentahydrate.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (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.'</p>
4625	SODIUM SILICATE	E	
4626	SODIUM STARCH GLYCOLLATE	E	
4627	SODIUM STARCH GLYCOLLATE TYPE A	E	
4628	SODIUM STEARATE	E	Only for use in topical medicines

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			for dermal application.
4629	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%.
4630	SODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4631	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4632	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%.
4633	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4634	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'.
4635	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'.

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4636	SODIUM SULFITE	E	
4637	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application.
4638	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%.
4639	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.
4640	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.
4641	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%.
4642	SOLANUM MELONGENA	A, H	When for internal use, steroidal

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			alkaloids calculated as solanine is a mandatory component of <i>Solanum melongena</i> . When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4643	SOLANUM NIGRUM	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of <i>Solanum nigrum</i> . When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4644	SOLANUM TUBEROSUM	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of <i>Solanum tuberosum</i> . When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4645	SOLIDAGO GIGANTEA	A, H	
4646	SOLIDAGO GIGANTEA MIS	A, E, H	
4647	SOLIDAGO VIRGAUREA	A, E, H	
4648	SOLUBLE MAIZE STARCH	E	
4649	SOLUBLE POTATO STARCH	E	
4650	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4651	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4652	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.

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4653	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%.
4654	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4655	SOPHORA FLAVESCENS	A, E, H	
4656	SOPHORA TONKINENSIS	A, H	
4657	SORBIC ACID	E	
4658	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4659	SORBITAN MONO-OLEATE	E	
4660	SORBITAN MONOLAURATE	E	
4661	SORBITAN MONOSTEARATE	E	
4662	SORBITAN OLEATE	E	
4663	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%.
4664	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%.
4665	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4666	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4667	SORBITAN STEARATE	E	
4668	SORBITAN TRISTEARATE	E	Only for use in topical medicines

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			for dermal application.
4669	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.
4670	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.
4671	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.
4672	SORBUS AUCUPARIA	A, H	
4673	SORGHUM	E	
4674	SORGHUM VULGARE	A, H	
4675	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy

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			lecithin liquid. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4676	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%.
4677	SOY POLYSACCHARIDE	E	
4678	SOY PROTEIN	E	
4679	SOY STEROL	E	
4680	SOYA BEAN	E	
4681	SOYA OIL	A, E, H	
4682	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%.
4683	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%.
4684	SPARGANIUM STOLONIFERUM	A, H	
4685	SPARTIUM JUNCEUM	A, H	
4686	SPATHOLOBUS SUBERECTUS	A, H	
4687	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

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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	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%.
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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

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			than 1 gram of menthol.
4689	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%.
4690	SPIGELIA ANTHELMIA	A, H	
4691	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4692	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

			<p>must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>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:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4693	SPINACH	E	
4694	SPINACIA OLERACEA	A, E, H	
4695	SPIRODELA POLYRRHIZA	A, H	
4696	SPIRULINA	E	
4697	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use as an excipient for oral routes of administration.
4698	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use as an excipient for oral routes of administration.
4699	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

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			flavour concentration in a medicine must be no more than 5%.
4700	SQUALANE	E	Only for use in topical medicines for dermal application.
4701	SQUALENE	A, E	
4702	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'.
4703	SQUILL DRY	A, H	
4704	SQUILL INDIAN DRY	A, H	
4705	SQUILL INDIAN POWDER	A, H	
4706	SQUILL POWDER	A, H	
4707	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.'
4708	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

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			doctor.'
4709	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.'
4710	STACHYS OFFICINALIS	A, E, H	
4711	STACHYS PALUSTRIS	A, H	
4712	STACHYURUS HIMALAICUS	A, H	
4713	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%.
4714	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4715	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).
4716	STARCH	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%.
4717	STARCH SODIUM OCTENYL SUCCINATE	E	
4718	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4719	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4720	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4721	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4722	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4723	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).
4724	STEARETH-10	E	Only for use in topical medicines for dermal application.
4725	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%.

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4726	STEARETH-2	E	Only for use in topical medicines for dermal application.
4727	STEARETH-20	E	Only for use in topical medicines for dermal application.
4728	STEARETH-21	E	Only for use in topical medicines for dermal application.
4729	STEARETH-5	E	Only for use in topical medicines for dermal application.
4730	STEARIC ACID	E	
4731	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%.
4732	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%.
4733	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4734	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4735	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4736	STEARYL ALCOHOL	E	
4737	STEARYL BEHENATE	E	Only for use as an excipient

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			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.
4738	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).
4739	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4740	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4741	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%.
4742	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4743	STELLARIA CHAMAEJASME	A, H	
4744	STELLARIA DICHOTOMA	A, H	
4745	STELLARIA MEDIA	A, E, H	

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4746	STEMONA JAPONICA	A, H	
4747	STEMONA SESSILIFOLIA	A, H	
4748	STENOTAPHRUM SECUNDATUM	A, H	
4749	STEPHANIA TETRANDA	A, H	
4750	STERCULIA	A, H	
4751	STERCULIA TRAGACANTHA	A, H	
4752	STERCULIA URENS	A, H	
4753	STEVIA REBAUDIANA	A, E, H	
4754	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4755	STILLINGIA SYLVATICA	A, H	
4756	STORAX PREPARED	A, E, H	
4757	STRAWBERRY	E	
4758	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%.
4759	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'.
4760	STREPTOCOCCUS THERMOPHILUS	A	
4761	STROBILANTHES CUSIA	A, H	

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4762	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%.
4763	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4764	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4765	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4766	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%.
4767	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%.
4768	STYPHNOLOBIUM JAPONICUM	A, E, H	
4769	STYRALLYL PROPIONATE	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary

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			excipient formulation in a medicine must not be more than 1%.
4770	STYRAX BENZOIN	A, E, H	
4771	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%.
4772	STYRAX PARALLELONEURUM	A, H	
4773	STYRAX TONKINENSIS	A, H	
4774	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%.
4775	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4776	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%.
4777	SUBLIMED SULFUR	H	Only for use as an active

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			homoeopathic ingredient.
4778	SUCCINIC ACID	E	
4779	SUCRALOSE	E	
4780	SUCROSE	E	
4781	SUCROSE ACETATE ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4782	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%.
4783	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%.
4784	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4785	SUCROSE LAURATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate.
4786	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.
4787	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.

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4788	SUCROSE POLYCOTTONSEEDATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (EYE) 'Avoid contact with the eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4789	SUCROSE STEARATE	E	<p>For use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>When for topical use, the concentration in the medicine must be no more than 0.25%.</p> <p>For oral use as a manufacturing aid only.</p> <p>When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit.</p>
4790	SUCROSE TRISTEARATE	E	<p>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.</p> <p>The concentration in the medicine must be no more than 2%.</p>
4791	SUDAN III	E	<p>Permitted for use only as a colour for topical use.</p>
4792	SUGAR CANE WAX ALCOHOLS	A, H	<p>The maximum recommended daily dose must not provide more than 12mg.</p> <p>The medicine requires the following warning statements on</p>

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			the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
4793	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of sugarcane.
4794	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4795	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%.
4796	SULFUR DIOXIDE	E	
4797	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4798	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%.
4799	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%.
4800	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

			<p>must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (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	SULISOBENZONE SODIUM	A	<p>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.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (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).
4802	SUNFLOWER OIL	A, E, H	
4803	SUNFLOWER SEED	E, H	
4804	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4805	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
4806	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines

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			for dermal application.
4807	SWEDE	E	
4808	SWEET ORANGE OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4809	SWEET POTATO	E	
4810	SWERTIA CHIRATA	A, H	
4811	SWIETENIA MAHOGANI	A, H	
4812	SYAGRUS ROMANZOFFIANA	A, E, H	
4813	SYMPHYOTRICHUM NOVI-BELGII	A, H	
4814	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%.
4815	SYMPLOCARPUS FOETIDUS	A, H	
4816	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4817	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.
4818	SYNTHETIC WAX	E	

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4819	SYRINGA RETICULATA	A, H	
4820	SYRINGA VULGARIS	A, H	
4821	SYZYGIUM AROMATICUM	A, E, H	<p>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:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>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.</p> <p>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.</p> <p>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%.</p>
4822	SYZYGIUM CUMINI	A, H	
4823	SYZYGIUM JAMBOS	E	Only for use in topical medicines

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			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%.
4824	TABEBUIA SERRATIFOLIA	A, E, H	
4825	TADEHAGI TRIQUETRUM	A, H	
4826	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%.
4827	TAGETES MINUTA	A, E, H	
4828	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%.
4829	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4830	TALLOW	E	Only for use in topical medicines for dermal application.
4831	TALLOW GLYCERIDES	E	
4832	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

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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%.
4833	TAMARIX APHYLLA	A, H	
4834	TAMARIX CHINENSIS	A, H	
4835	TAMARIX GALLICA	A, H	
4836	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.
4837	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4838	TANACETUM COCCINEUM SUBSP. COCCINEUM	A, H	
4839	TANACETUM PARTHENIUM	A, E, H	
4840	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%.
4841	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%.

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4842	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.
4843	TANNIC ACID	E	
4844	TAPIOCA STARCH	E	
4845	TARAXACUM MONGOLICUM	A, E, H	
4846	TARAXACUM OFFICINALE	A, E, H	
4847	TARO	E	
4848	TARRAGON OIL	A, E, H	
4849	TARTARIC ACID	E	
4850	TARTRAZINE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4851	TARTRAZINE ALUMINIUM LAKE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4852	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%.
4853	TAURINE	A, E	
4854	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4855	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

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			<p>bark or its extract equivalents.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (CHILD2) 'Not suitable for children'.
4856	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4857	TERMINALIA CATAPPA	A, H	
4858	TERMINALIA CHEBULA	A, H	
4859	TERMINALIA FERDINANDIANA	A, E, H	<p>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.</p> <p>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.</p> <p>When used as an excipient, the concentration in the medicine must be no more than 0.3%.</p>
4860	TERMINALIA SERICEA	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>Only for use when the plant part is root bark.</p> <p>Only methanol/water (90:10; V/V) extract of Terminalia sericea bark of the root is approved.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
4861	TERPENE RESIN	E	Terpene resin must only be

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			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.
4862	TERPINEN-4-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4863	TERPINEOL	E	
4864	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%.
4865	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%.

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4866	TERPINYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4867	TERPINYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4868	TERPINYL METHYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
4869	TERT-BUTYL ALCOHOL	E	<p>Only for use in topical medicines for dermal application.</p>
4870	TERT-BUTYL HYDROQUINONE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
4871	TERT-BUTYL METHYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a</p>

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			fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4872	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%.
4873	TETRACLINIS ARTICULATA	A, E, H	
4874	TETRADECYL AMINOBUTYROYLVALYLAMIN OBUTYRIC 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%.
4875	TETRADIMUM 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.
4876	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%.
4877	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

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				1%.
4878	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%.	
4879	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%.	
4880	TETRAHYDRODIFERULOYLME THANE	E	Only for use in topical medicines for dermal 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%.	
4881	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%.	
4882	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	

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			1%.
4883	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%.
4884	TETRAHYDROMUGUOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4885	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%.
4886	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4887	TETRAMETHYL ACETYLOCTAHYDRONAPHTHA LENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4888	TETRAPANAX PAPYRIFER	A, H	
4889	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines

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for dermal application.			
4890	TETRASODIUM PYROPHOSPHATE	E	
4891	TEUCRIUM CHAMAEDRYIS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4892	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4893	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4894	THAPSIA GARGANICA	A, H	
4895	THAUMATIN	E	
4896	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%.
4897	THEMEDA TRIANDRA	A, H	
4898	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.'

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			- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
4899	THEOBROMA OIL	A, E, H	
4900	THIAMINE	A, E	
4901	THIAMINE HYDROCHLORIDE	A, E	
4902	THIAMINE NITRATE	A, E	
4903	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%.
4904	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%.
4905	THLASPI ARVENSE	A, E, H	
4906	THREONINE	A, E	
4907	THUJA OCCIDENTALIS	A, H	
4908	THUJA PLICATA	A, E, H	
4909	THYME HERB DRY	A, E, H	
4910	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).

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4911	THYMOL	A, E	<p>When used as an active ingredient, the medicine must be medicated space spray or medicated throat lozenges.</p> <p>When used as an excipient, only for use in medicated throat lozenges or topical medicines for dermal applications.</p>
4912	THYMOL METHYL ETHER	E	<p>Thymol methyl ether must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of the flavour proprietary excipient formulation containing thymol methyl ether must not be more than 5% of the total medicine.</p>
4913	THYMUS CAPITATUS	A, E, H	<p>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:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
4914	THYMUS GLAND	H	<p>Only for use as an active homoeopathic ingredient.</p>
4915	THYMUS MASTICHINA	A, E, H	<p>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</p>

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			warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4916	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).
4917	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).
4918	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

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			(c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4919	THYMUS ZYGIS	A, H	When the plant preparation is an oil or a distillate, and the concentration of Thymus zygis oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4920	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4921	TILACTASE	A	Must be derived from <i>Aspergillus oryzae</i> and comply with the relevant USP monograph.
4922	TILIA CORDATA	A, E, H	
4923	TILIA PLATYPHYLLOS	A, E, H	
4924	TILIA TOMENTOSA	A, H	
4925	TILIA X VULGARIS	A, E, H	
4926	TILIANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4927	TIN	H	Only for use as an active homoeopathic ingredient.

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4928	TINOSPORA CORDIFOLIA	A, H	
4929	TINOSPORA SINENSIS	A, H	
4930	TITANIUM DIOXIDE	A, E	<p>For use as an active ingredient only in sunscreens for dermal application.</p> <p>The concentration in sunscreens must be no more than 25%.</p> <p>For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration.</p> <p>Not to be included in medicines intended for use in the eye.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (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).
4931	TOCOCYSTEAMIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.01%.</p>
4932	TOCOFERSOLAN	E	<p>Only for oral and topical use.</p> <p>When for oral use, the concentration in the medicine must be no more than 10% w/w.</p> <p>When used in topical medicines for dermal application, it is not to be included in medicines intended for use in the eye.</p> <p>When for topical use, the concentration in the medicine must be no more than 0.1%</p>

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4933	TOCOPHEROL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4934	TOCOPHERYL GLUCOSIDE	E	<p>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.</p> <p>The concentration in the medicine must be no more than 0.05%</p>
4935	TOCOPHERYL LINOLEATE	E	<p>Only for use in topical medicines for dermal application.</p>
4936	TOCOPHERYL NICOTINATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration must not exceed 0.3%.</p>
4937	TOLU BALSAM	A, E, H	
4938	TOLUENE	E	<p>The residual solvent limit for toluene is 8.9 mg per maximum recommended daily dose.</p> <p>The concentration in the medicine must be no more than 0.089%.</p>
4939	TOLYL ALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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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%.
4940	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%.
4941	TOMATO	E	
4942	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%.
4943	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%.
4944	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%.

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4945	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4946	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.
4947	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4948	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4949	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4950	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%.
4951	TRAGACANTH	A, E	

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4952	TRAMETES VERSICOLOR	A, H	
4953	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4954	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%.
4955	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.
4956	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%.
4957	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%.

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4958	TRANS-2-DODECENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4959	TRANS-2-HEPTEN-1-AL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4960	TRANS-2-HEXENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4961	TRANS-2-HEXENOIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4962	TRANS-2-HEXENOL	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4963	TRANS-2-HEXENYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4964	TRANS-2-HEXENYL PHENYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4965	TRANS-2-HYDROXYCINNAMIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4966	TRANS-2-OCTENAL	E	<p>trans-2-Octenal must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing trans-2-</p>

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			octenal must not be more than 1% of the total medicine.
4967	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%.
4968	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%.
4969	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%.
4970	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%.
4971	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

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			5%.
4972	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%.
4973	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of treacle.
4974	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%.
4975	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.

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			Only able to be used when presented in single use sachets for therapeutic use as an iron supplement.
4976	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.
4977	TREMELLA FUCIFORMIS	A, H	
4978	TRIACETIN	E	
4979	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4980	TRIADICA SEBIFERA	A, H	
4981	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.
4982	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.
4983	TRIBEHENIN	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4984	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%.
4985	TRIBULUS TERRESTRIS	A, E, H	
4986	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%.
4987	TRICALCIUM PHOSPHATE	E	
4988	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%.
4989	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%.
4990	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4991	TRICHLOROMETHYLPHENYLARBINYL ACETATE	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%.
4992	TRICHODERMA VIRIDE	A, E, H		
4993	TRICHOSANTHES KIRILOWII	A, E, H		
4994	TRICLOSAN	E		The concentration in the medicine must be no more than 1%.
4995	TRICYCLODECENYL PROPIONATE	E		Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4996	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%.
4997	TRIDECETH-4 PHOSPHATE	E		Only for use in topical medicines for dermal application.
4998	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%.
4999	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

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			1%.
5000	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
5001	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%.
5002	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%.
5003	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
5004	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
5005	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%.
5006	TRIETHYL CITRATE	E	
5007	TRIETHYLENE GLYCOL	E	
5008	TRIFOLIUM PRATENSE	A, E, H	
5009	TRIFOLIUM REPENS	A, H	
5010	TRIGONELLA FOENUM- GRAECUM	A, E, H	

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5011	TRIHYDROXPALMITAMIDOH YDROXYPROPYL 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%.
5012	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
5013	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
5014	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%.
5015	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%.
5016	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
5017	TRILAURIN	E	Only for use in topical medicines for dermal application.
5018	TRILISA ODORATISSIMA	A, H	
5019	TRILLIUM ERECTUM	A, H	
5020	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%.

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5021	TRIMETHYL HYDROXPENTYL 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%.
5022	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%.
5023	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%.
5024	TRIMETHYLBENZENEPROPANO L	E	Permitted for use only in combination with 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	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%.
5026	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.

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5027	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%.
5028	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5029	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%.
5030	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%.
5031	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%.
5032	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%.
5033	TRIOSTEUM PERFOLIATUM	A, H	
5034	TRIOXAUNDECANEDIOIC ACID	E	
5035	TRIPAL	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%.
5036	TRIPLEPTIDE-1	E	<p>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.</p> <p>The concentration in the medicine must be no more than 0.002%.</p>
5037	TRIS-BIPHENYL TRIAZINE	A	<p>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.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used topically, the dosage form must not be spray.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (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).
5038	TRISILOXANE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 40%.</p>
5039	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.

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5040	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%.
5041	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%.
5042	TRISTEARIN	E	
5043	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.
5044	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.
5045	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%.
5046	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5047	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
5048	TROLAMINE SALICYLATE	A	Only for use as an active

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			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).
5049	TROLLIUS CHINENSIS	A, H	
5050	TROMETAMOL	E	
5051	TROMETAMOL HYDROCHLORIDE	E	
5052	TROPAEOLUM MAJUS	A, E, H	
5053	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5054	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%.
5055	TSUGA CANADENSIS	A, H	
5056	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%.
5057	TURMERIC	E	Permitted for use only in

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			combination with other permitted ingredients as a colour.
5058	TURNERA DIFFUSA	A, E, H	<p>Beta-arbutin is a mandatory component of Turnera diffusa.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>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%.</p>
5059	TURNIP	E	
5060	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than 25%.
5061	TYPHA ANGUSTIFOLIA	A, H	
5062	TYPHA LATIFOLIA	A, H	
5063	TYPHONIUM GIGANTEUM	A, H	
5064	TYROSINE	A, E	