

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 than 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> <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).

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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.' - (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	

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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%.
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	

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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 fragrance. If used in a 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%.
3675	PARA-CRESYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
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 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3679	PARA-ETHOXYBENZALDEHYDE	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>
3680	PARA-ETHYL CRESOXYACETATE	E	<p>Para-ethyl cresoxyacetate 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 para-ethyl cresoxyacetate</p>

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			must not be more than 1% of the total medicine.
3681	PARA-ETHYLPHENOL	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The maximum recommended daily dose must contain no more than 0.12 mg of para-ethylphenol.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
3682	PARA-HYDROXY BENZALACETONE	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>
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 than 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 than 1%.</p>

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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 fragrance concentration in a medicine must be no more than 1%.</p>
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>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
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> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
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	Permitted for use only in combination with other permitted ingredients as a flavour.

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			If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
3704	PARTIALLY REFINED PORPHYRA YEZOENSIS CYTOPLASM EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.00002%.
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

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concentration of total caffeine greater than 33%.

When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.

When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).
- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'
- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'
- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult

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			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%.
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.

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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: - (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.

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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	<p>Only for use in topical medicines for dermal application.</p> <p>Dioxane and Ethylene oxide are mandatory components of PEG-4 laurate.</p> <p>The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.</p>
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	<p>Only for use in topical medicines for dermal application.</p> <p>Dioxane and Ethylene oxide are mandatory components of PEG-40 sorbitan diisostearate.</p> <p>The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.</p>
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.

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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%.
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.

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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 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.

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			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%.
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

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			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 TETRAISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 61%.
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 than 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%.

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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 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

			<p>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>
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> <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</p>

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			must not contain more than 1 gram of menthol.
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 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> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
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 than 1%.</p>

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			<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 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 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-DIMETHYL-BENZO [B] FURAN-2-ONE	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>
3793	PERILLA FRUTESCENS	A, E, H	
3794	PERILLALDEHYDE	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>
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	

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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 flavour concentration in a medicine must be no more than 5%</p>
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 than 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	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p>

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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>
3808	PETROSELINUM CRISPUM	A, E, H	
3809	PEUCEDANUM PRAERUPTORUM	A, E, H	
3810	PEUMUS BOLDUS	A, H	<p>Volatile oil components (of Peumus boldus) is a mandatory component.</p> <p>The maximum recommended daily dose must be no more than 100 mg of volatile oil components (of Peumus boldus).</p>
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	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
3819	PHENETHYL 2-METHYLBUTYRATE	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>
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> <p>If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
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>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
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	<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>
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	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%.
3831	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The concentration of phenoxyethanol in the preparation must not exceed 15%.
3832	PHENOXYETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3833	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
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 than 1%.
3837	PHENYLACETALDEHYDE DIMETHYL ACETAL	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>
3838	PHENYLACETALDEHYDE GLYCERYLACETAL	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>
3839	PHENYLACETIC 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>
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>

			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
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 5%.</p>
3843	PHENYLETHYL CAPROATE	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>
3844	PHENYLETHYL CAPRYLATE	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>
3845	PHENYLETHYL CINNAMATE	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>
3846	PHENYLETHYL FORMATE	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%.
3847	PHENYLETHYL METHYLETHYL 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>
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	Only permitted in preparations other than phleum pratense pollen extract.

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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	PICRAMIS 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 be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.21%.

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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.
3888	PILOCARPUS JABORANDI	A, H	Pilocarpine is a mandatory component of Pilocarpus jaborandi. The concentration of pilocarpine in the medicine must be no more than 0.025%.

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3889	PILOCARPUS MICROPHYLLUS	A, H	<p>Pilocarpine is a mandatory component of <i>Pilocarpus microphyllus</i>.</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 <i>Pilocarpus pinnatifolius</i>.</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 <i>Pimenta racemosa</i> 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 <i>Pimenta racemosa</i> 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 <i>Pimenta racemosa</i> is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container.</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 <i>Pimpinella anisum</i> is an oil or distillate and the concentration of this oil or</p>

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			distillate in the medicine is more than 50%: a) the nominal capacity of the container must be no more than 50 millilitres; and b) a restricted flow insert is must be fitted on the container; and c) the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3896	PIMPINELLA SAXIFRAGA	A, E, H	
3897	PINE NEEDLE OIL SCOTCH	A, E, H	
3898	PINE NEEDLE OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3899	PINE OIL AROMATIC	A, E, H	
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%

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			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 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%.

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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	<p>Kavalactones (of Piper methysticum) is a mandatory component of Piper methysticum.</p> <p>Only for oral use when the dosage form is 'tablet' or 'capsule'; or when the container type is 'tea bag'.</p> <p>When used in oral medicines, the maximum daily dose of kavalactones (of Piper methysticum) must be no more than 250 mg.</p> <p>If the dosage form is tablet or capsule then the quantity of kavalactones (of Piper methysticum) must be no more than 125 mg per tablet or capsule.</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</p>

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			no more than 3 grams of dried whole or peeled root or rhizomes.
3923	PIPER NIGRUM	A, E, H	
3924	PIPER SARMENTOSUM	A, E, H	
3925	PIPERINE	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary formulation. The total flavour proprietary formulation in a medicine must not be more than 5% and the concentration of piperine in the medicine must not be more than 0.15%.
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 than 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.

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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. 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'

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			When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3939	PLANTAGO 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 may be dangerous if taken in large amounts or for a long period' (or words to that effect).</p>

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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 the effect of other medication.'; 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 Aspergillus niger is only</p>

			permitted for use in topical medicines for dermal application.
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> <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.' <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p>
3962	POLLEN	E	The medicine requires the following warning statement on the medicine label:

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			- (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect).
3963	POLOXAMER	E	Only for use in topical medicines for dermal application.
3964	POLOXAMINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3965	POLY C10-30 ALKYL ACRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3966	POLYACRYLAMIDE	E	Only for use in topical medicines for dermal application. Acrylamide is a mandatory component of Polyacrylamide. The concentration of Acrylamide in the medicine must be no more than 0.01%.
3967	POLYACRYLATE CROSSPOLYMER-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3968	POLYACRYLATE-1 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.4%.
3969	POLYACRYLIC ACID	E	

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3970	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3971	POLYAMINOPROPYL BIGUANIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.
3972	POLYBUTADIENE	E	Only for use as part of an adhesive in topical medicines for dermal application.
3973	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3974	POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3975	POLYCAPROLACTONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3976	POLYDECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3977	POLYDEXTROSE	E	
3978	POLYDIETHYLSILOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.

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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 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.

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3988	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
3989	POLYGLYCERYL-10 PENTASTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3990	POLYGLYCERYL-2 CAPRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. The concentration in the medicine must not be more than 0.5%.
3991	POLYGLYCERYL-2 DIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3.0%.
3992	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3993	POLYGLYCERYL-2 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 3%.
3994	POLYGLYCERYL-2 ISOSTEARATE	E	Polyglyceryl-2 isostearate must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin or in the eye. The concentration in the medicine must be no more than 2.5%.

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3995	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%.
3996	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3997	POLYGLYCERYL-3 BEESWAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.
3998	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
3999	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%.
4000	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%.
4001	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%.

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4002	POLYGLYCERYL-3 POLYRICINOLEATE	E	
4003	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIMER DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4004	POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYST EARATE/SEBACATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4005	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%.
4006	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
4007	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%.
4008	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
4009	POLYGONATUM MULTIFLORUM	A, H	
4010	POLYGONATUM OFFICINALE	A, H	
4011	POLYGONATUM SIBIRICUM	A, E, H	
4012	POLYGONUM AVICULARE	A, E, H	When used as an excipient, the medicine is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye.

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			When used as an excipient, the concentration in the medicine must be no more than 0.16%.
4013	POLYGONUM BISTORTA	A, H	
4014	POLYGONUM ODORATUM	A, H	
4015	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
4016	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.
4017	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
4018	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%.
4019	POLYMETHACRYLIC ACID	E	
4020	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%.

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4021	POLYMETHYLSILSESQUIOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4022	POLYPORUS UMBELLATUS	A, H	
4023	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
4024	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%.
4025	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
4026	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4027	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%.
4028	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
4029	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.

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4030	POLYQUATERNIUM-37	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4031	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%.
4032	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%.
4033	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%.
4034	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
4035	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%
4036	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%.
4037	POLYSILICONE-15	A	Only for use as an active ingredient in sunscreens for dermal application and

			<p>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).
4038	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>
4039	POLYSORBATE 20	E	
4040	POLYSORBATE 40	E	
4041	POLYSORBATE 60	E	
4042	POLYSORBATE 65	E	
4043	POLYSORBATE 80	E	
4044	POLYSORBATE 85	E	<p>Only for use in topical medicines for dermal application.</p>
4045	POLYSTYRENE	E	<p>Only for use as part of an adhesive in topical medicines for dermal application.</p>
4046	POLYTEF	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>
4047	POLYURETHANE-34	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>

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			The concentration in the medicine must be no more than 2% in spray applications and 6% in non-spray applications.
4048	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%.
4049	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4050	POLYVINYL ACETATE PHTHALATE	E	
4051	POLYVINYL ALCOHOL	E	
4052	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4053	POMEGRANATE	E	
4054	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4055	PONCIRUS TRIFOLIATA	A, H	When used internally, oxedrine is a mandatory component of Poncirus trifoliata. The quantity of Oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4056	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%.
4057	PONTEDERIA CRASSIPES	A, H	
4058	POPPY SEED	E, H	
4059	POPPY SEED OIL	E, H	
4060	POPULUS ALBA	A, H	
4061	POPULUS BALSAMIFERA	A, E, H	
4062	POPULUS CANDICANS	A, H	

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4063	POPULUS DELTOIDES	A, H	
4064	POPULUS NIGRA	A, H	
4065	POPULUS TREMULA	A, H	
4066	POPULUS TREMULOIDES	A, H	
4067	PORCINE	H	Only for use as an active homoeopathic ingredient.
4068	PORPHYRIDIVM 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%.
4069	PORTULACA OLERACEA	A, E, H	
4070	POTABLE WATER	E	
4071	POTASSIVM ACETATE	E	
4072	POTASSIVM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4073	POTASSIVM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4074	POTASSIVM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4075	POTASSIVM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4076	POTASSIVM 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.
4077	POTASSIVM 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

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			potassium from potassium aspartate dihydrate should be calculated based on the molecular weight of potassium aspartate dihydrate.
4078	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.
4079	POTASSIUM BICARBONATE	E	
4080	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%.
4081	POTASSIUM CARBONATE	E, H	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4082	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4083	POTASSIUM CHLORIDE	A, E, H	When for oral use: (a) potassium is a mandatory component of potassium chloride; (b) the medicine requires the following warning statement on the medicine label: - (POTAS1) 'If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and

			<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 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> <ul style="list-style-type: none"> - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' <p>When for dental use, the concentration of potassium chloride in the medicine must not be more than 3.75%.</p>
4084	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.
4085	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>

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4086	POTASSIUM COCOYL HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.
4087	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4088	POTASSIUM GLUCONATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium gluconate.
4089	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.
4090	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.
4091	POTASSIUM HYDROXYCITRATE	A, H	
4092	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

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			no more than 337 micrograms of potassium iodate.
4093	POTASSIUM IODIDE	A, E, H	<p>Iodine is a mandatory component of potassium iodide.</p> <p>The percentage of iodine from potassium iodide should be calculated based on the molecular weight of potassium iodide.</p> <p>When for internal use, the maximum recommended daily dose of the medicine must contains 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>
4094	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>
4095	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>
4096	POTASSIUM NITRATE	A, H	<p>Only for dental use.</p> <p>The concentration in the medicine must be no more than 5%.</p>
4097	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>

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			When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4098	POTASSIUM PYROPHOSPHATE	E	Only for oral application, dental or topical use. Not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4099	POTASSIUM SORBATE	E	
4100	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%.
4101	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4102	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.
4103	POTATO STARCH	E	
4104	POTENTILLA ANSERINA	A, H	
4105	POTENTILLA CHINENSIS	A, H	
4106	POTENTILLA DISCOLOR	A, H	
4107	POTENTILLA ERECTA	A, E, H	
4108	POTENTILLA REPTANS	A, H	
4109	POTERIUM OFFICINALE	A, E, H	

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4110	POTERIUM SANGUISORBA	A, H	
4111	POVIDONE	E	
4112	POWDERED CELLULOSE	E	
4113	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%.
4114	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%.
4115	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%.
4116	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%.
4117	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%.
4118	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4119	PPG-2 MYRISTYL ETHER PROPIONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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			The concentration in the medicine must be no more than 5%.
4120	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4121	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%.
4122	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4123	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%.
4124	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4125	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4126	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4127	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%.
4128	PREGELATINISED MAIZE STARCH	E	
4129	PREGELATINISED POTATO STARCH	E	
4130	PREGELATINISED RICE STARCH	E	
4131	PREGELATINISED STARCH	E	

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4132	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4133	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 than 1%.
4134	PRICKLY ASH BARK DRY	A, H	
4135	PRICKLY ASH BARK POWDER	A, H	
4136	PRIMULA VERIS	A, E, H	
4137	PRIMULA VULGARIS	A, E, H	
4138	PRINSEPIA UNIFLORA	A, H	
4139	PROBOSCIDEA PARVIFLORA	A, H	
4140	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%.
4141	PROLINE	A, E	
4142	PROPAN-1-OL	E	Only for use in: - topical medicines for dermal application; or - in combination with other permitted ingredients as a flavour proprietary excipient formulation. The concentration of propan-1-ol in the medicine must not be more than 18%. When used in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation, the total flavour proprietary excipient formulation in a medicine must not be more than 5%.

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4143	PROPANE	E	Only for use as an excipient propellant ingredient.
4144	PROPANEDIOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%.
4145	PROPENYL GUAETHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4146	PROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4147	PROPIONIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4148	PROPIONYLLEVO-CARNITINE HYDROCHLORIDE	A, H	

4149	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:</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 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 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 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>

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			<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 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> <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 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>

4154	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 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>
4155	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>
4156	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>
4157	PROPYL GALLATE	E	
4158	PROPYL HYDROXYBENZOATE	E	
4159	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4160	PROPYLENE GLYCOL	E	
4161	PROPYLENE GLYCOL ALGINATE	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%.
4162	PROPYLENE GLYCOL DIBENZOATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 20%.
4163	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%.
4164	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4165	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4166	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4167	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%.
4168	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4169	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4170	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.

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4171	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4172	PROSOPIS JULIFLORA	A, H	
4173	PROTEASE	A	Must be derived from <i>Aspergillus oryzae</i> or <i>Aspergillus niger</i> .
4174	PROTEIN HYDROLYSATE	E	
4175	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%.
4176	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%.
4177	PRUNELLA VULGARIS	A, H	
4178	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%.
4179	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

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			microgram/kg or 1 microgram/L or 0.0000001%.
4180	PRUNUS AVIUM	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus avium.</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 CERASIFERA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera.</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 CERASUS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasus.</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 DOMESTICA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica.</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>

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4184	PRUNUS DULCIS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus dulcis 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>
4185	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>
4186	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>
4187	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>

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4188	PRUNUS MUME	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of 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>
4189	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>
4190	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>
4191	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>
4192	PRUNUS SPINOSA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa.</p>

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			<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>
4193	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4194	PSEUDOCYDONIA SINENSIS	A, H	
4195	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4196	PSEUDOTSUGA MENZIESII	A, H	
4197	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4198	PSIDIUM GUAJAVA	A, E, H	
4199	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4200	PSYLLIUM HUSK DRY	A, H	<p>When a dose for children is stated, the following warning statement is required on the label:</p> <p>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</p>
4201	PSYLLIUM HUSK POWDER	A, E, H	<p>When a dose for children is stated, the following warning statement is required on the label:</p> <p>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</p>
4202	PSYLLIUM SEED DRY	A, E, H	<p>When a dose for children is stated the following warning statement is required on the label:</p> <p>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</p>
4203	PTELEA TRIFOLIATA	A, H	

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4204	PTEROCARPUS MARSUPIUM	A, H	
4205	PTEROCARPUS SANTALINUS	A, E, H	
4206	PUERARIA LOBATA	A, E, H	
4207	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4208	PULLULAN	E	
4209	PUMICE	E	
4210	PUMPKIN	E	
4211	PUMPKIN SEED OIL	E, H	
4212	PUNICA GRANATUM	A, E, H	
4213	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4214	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).
4215	PURIFIED SILICEOUS EARTH	E, H	
4216	PURIFIED TALC	E	
4217	PURIFIED WATER	E	
4218	PVM/MA COPOLYMER	E	
4219	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4220	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4221	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4222	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).
4223	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>
4224	PYRIDOXAL 5-PHOSPHATE MONOHYDRATE	A	<p>Pyridoxine is a mandatory 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>

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			<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	PYRIDOXINE HYDROCHLORIDE	A, E, H	<p>When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of pyridoxine hydrochloride.</p> <p>The percentage of pyridoxine 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</p>

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			10 mg of pyridoxine, the following warning statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
4226	PYROGLUTAMIC ACID	E	
4227	PYROLA DECORATA	A, H	
4228	PYROLIGNEOUS ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4229	PYRROSIA LINGUA	A, H	
4230	PYRROSIA PETIOLOSA	A, H	
4231	PYRROSIA SHEARERI	A, H	
4232	PYRUS COMMUNIS	A, E, H	Beta-arbutin is a mandatory component of <i>Pyrus communis</i> . 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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4233	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 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>
4234	PYRUVIC 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>
4235	QUASSIA	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>
4236	QUASSIA AMARA	A, E, H	
4237	QUASSIA WOOD JAMAICAN DRY	A, H	
4238	QUASSIA WOOD JAMAICAN POWDER	A, H	
4239	QUATERNIUM-15	E	<p>Only for use in topical medicines for dermal application.</p>

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4240	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4241	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4242	QUATERNIUM-52	E	Only for use in wash-on/wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. Not be used in medicines in which N-nitroso compounds may be formed.
4243	QUATERNIUM-80	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4244	QUERCETIN	A	
4245	QUERCETIN DIHYDRATE	A	
4246	QUERCUS ACUTISSIMA	A, H	
4247	QUERCUS ALBA	A, E, H	
4248	QUERCUS PALUSTRIS	A, H	
4249	QUERCUS ROBUR	A, H	
4250	QUERCUS RUBRA	A, H	
4251	QUERCUS VIRGINIANA	A, H	
4252	QUILLAIA DRY	A, H	
4253	QUILLAIA POWDER	A, E, H	
4254	QUILLAIA SAPONARIA	A, H	
4255	QUINCE	E	
4256	QUININE ARSENITE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of Quinine arsenite. The maximum recommended daily dose must be no more than 50 mg of quinine.

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4257	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> <p>The maximum recommended daily dose must be no more than 50 mg of quinine.</p>
4258	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4259	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4260	QUISQUALIS INDICA	A, H	
4261	R-ALPHA LIPOIC ACID	A	
4262	RACEMENTHOL	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>
4263	RACEMIC CAMPHOR	E, H	<p>Only for use as an active homoeopathic or excipient ingredient.</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, the concentration of camphor must be no more than 2.5%.</p> <p>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:</p>

			<p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <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> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <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> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <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>
4264	RADISH	E	
4265	RAISIN JUICE CONCENTRATE	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>
4266	RANUNCULUS BULBOSUS	A, H	
4267	RANUNCULUS FICARIA	A, H	
4268	RANUNCULUS TERNATUS	A, H	

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4269	RAPE SEED OIL	A, E, H	<p>Allyl isothiocyanate is a mandatory component of rape seed oil when the plant part is seed.</p> <p>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%.</p>
4270	RAPHANUS SATIVUS	A, H	
4271	RASPBERRY	E	
4272	RASPBERRY BRANDY	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>
4273	RASPBERRY DISTILLATE	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>
4274	RASPBERRY FRUIT 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>
4275	RASPBERRY JUICE CONCENTRATE	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>
4276	RAUWOLFIA SERPENTINA	A, H	<p>The concentration of equivalent dry Rauwolfia serpentina in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.</p>

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4277	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%.
4278	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%.
4279	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%.
4280	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%.
4281	RED ANT	H	Only for use as an active homoeopathic ingredient.
4282	RED CLOVER FLOWER DRY	A, H	
4283	RED CLOVER FLOWER POWDER	A, H	
4284	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4285	RED DEER	A	
4286	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4287	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4288	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.

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4289	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>
4290	REHMANNIA GLUTINOSA	A, E, H	
4291	REL-1-((1R,2S)-1,2,3,4,5,6,7,8-OCTAHYDRO-1,2,8,8-TETRAMETHYL-2-NAPHTHALENYL)-1-ETHANONE	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>
4292	RESORCINOL	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>

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4293	RESORCINOL DIMETHYLETHER	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>
4294	RESVERATROL	A	<p>Only permitted for use in medicines that are for oral routes of administration.</p> <p>The maximum recommended daily dose of the medicine must not contain more than 150 milligrams of resveratrol.</p> <p>The following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (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'.
4295	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> <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

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			<p>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>
4296	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> <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	RETINOL PALMITATE	A, E	<p>Vitamin A is a mandatory component of retinol palmitate.</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>
4298	REYNOUTRIA JAPONICA	A, E, H	<p>When used as an excipient, only for use in topical medicines for dermal application.</p>
4299	RHAMNOSE	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>

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4300	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>
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			<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	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). <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</p>

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			contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4302	RHATANY ROOT DRY	A, H	
4303	RHATANY ROOT POWDER	A, H	
4304	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: - (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> <p>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).</p> <p>When not promoted or marketed as laxative, the medicine requires the</p>

			<p>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'.
4305	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> <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).

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			<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>
4306	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> <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> <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>
4307	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</p>

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hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:

- (CHILD3) 'Use in children under 12 years is not recommended';
- (LAX2) 'Prolonged use may cause serious bowel problems'; and
- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).

When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:

- (LAX1) 'Drink plenty of water' (or words to that effect).

When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and
- (LAX4) 'This product may have laxative effect'.

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

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

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4308	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4309	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 than 1%.</p>
4310	RHODINYL ACETATE	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>
4311	RHODIOLA ROSEA	A	<p>Only for use in oral medicines.</p> <p>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.</p>
4312	RHODODENDRON AUREUM	A, H	
4313	RHODODENDRON FERRUGINEUM	A, H	<p>Beta-arbutin is a mandatory component of <i>Rhododendron ferrugineum</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>

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			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%.
4314	RHODODENDRON GROENLANDICUM	A, H	
4315	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4316	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'; 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>

			<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>
4317	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 the medicine label:</p>

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			<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>
4318	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> <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</p>

			<p>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>
4319	RHUS AROMATICA	A, E, H	
4320	RHUS CHINENSIS	A, H	
4321	RHUS GLABRA	A, E, H	
4322	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4323	RIBES GROSSULARIA	A, E, H	
4324	RIBES NIGRUM	A, E, H	
4325	RIBOFLAVIN	A, E	
4326	RIBOFLAVIN SODIUM PHOSPHATE	A, E	

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4327	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4328	RIBOFLAVINE	A, E	
4329	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4330	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4331	RIBOSE	A	Only for use in oral medicines.
4332	RICE	E	
4333	RICE BRAN	E	
4334	RICE BRAN OIL	E	
4335	RICE BRAN WAX	A, E, H	
4336	RICE STARCH	E	
4337	RICE VINEGAR	E	
4338	RICE WINE	E	Ethanol is a mandatory component of rice wine.
4339	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4340	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4341	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.
4342	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4343	ROSA ARVENSIS	A, E, H	
4344	ROSA CANINA	A, E, H	
4345	ROSA CYMOSA	A, E, H	

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4346	ROSA EGLANTERIA	A, E, H	
4347	ROSA GALLICA	A, E, H	
4348	ROSA LAEVIGATA	A, E, H	
4349	ROSA MULTIFLORA	A, E, H	
4350	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%.
4351	ROSA RUGOSA	A, E, H	
4352	ROSA VILLOSA	A, E, H	
4353	ROSA X CENTIFOLIA	A, E, H	
4354	ROSA X DAMASCENA	A, E, H	
4355	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%.
4356	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 than 1%.
4357	ROSE FRUIT FRESH	A, E, H	
4358	ROSE HIP	E	
4359	ROSE OIL	A, E, H	
4360	ROSE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4361	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>
4362	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 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:</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 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,</p>

			<p>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>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4363	ROYAL JELLY	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly. The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHIL2) '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 FRESH	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh. The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHIL2) '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'.

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4365	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'.
4366	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4367	RUBIA CORDIFOLIA	A, H	
4368	RUBIA TINCTORUM	A, H	
4369	RUBUS CHINGII	A, H	
4370	RUBUS CORCHORIFOLIUS	A, H	
4371	RUBUS COREANUS	A, E, H	
4372	RUBUS FRUTICOSUS	A, E, H	
4373	RUBUS IDAEUS	A, E, H	
4374	RUBUS OCCIDENTALIS	A, E, H	
4375	RUBUS PARVIFOLIUS	A, H	
4376	RUBUS ROSIFOLIUS	A, H	
4377	RUDBECKIA HIRTA	A, H	
4378	RUE OIL	A, H	
4379	RUM	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>
4380	RUMEX ACETOSA	A, H	
4381	RUMEX ACETOSELLA	A, H	
4382	RUMEX CONGLOMERATUS	A, H	

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4383	RUMEX CRISPUS	A, E, H	
4384	RUMEX PULCHER	A, H	
4385	RUMEX SCUTATUS	A, H	
4386	RUSCUS ACULEATUS	A, H	
4387	RUTA GRAVEOLENS	A, E, H	
4388	RUTOSIDE	A, E	
4389	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4390	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.
4391	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%.
4392	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.
4393	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%.
4394	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.

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			The concentration in the medicine must be no more than 3.66%.
4395	SACCHARIN	E	
4396	SACCHARIN SODIUM	E	
4397	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4398	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4399	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%.
4400	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4401	SACCHARUM OFFICINARUM	A, E, H	
4402	SAFFLOWER OIL	A, E, H	
4403	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4404	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%.
4405	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%.
4406	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%.

			<p>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:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
4407	SAGE OIL SPANISH	A, E, H	
4408	SALICORNIA EUROPAEA EXTRACT	E	<p>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.</p> <p>The concentration in the medicine must be no more than 0.002%.</p>
4409	SALICYLALDEHYDE	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>
4410	SALICYLIC ACID	E, H	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 40%.</p>
4411	SALIX ALBA	A, E, H	
4412	SALIX DAPHNOIDES	A, H	
4413	SALIX DISCOLOR	A, H	
4414	SALIX FRAGILIS	A, H	
4415	SALIX NIGRA	A, H	
4416	SALIX PURPUREA	A, H	

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4417	SALSOLA KALI	A, H	
4418	SALVIA CHINENSIS	A, H	
4419	SALVIA FRUTICOSA	A, H	
4420	SALVIA HISPANICA	A, E, H	
4421	SALVIA LAVANDULAEFOLIA	A, H	
4422	SALVIA MILTIORRHIZA	A, H	
4423	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%.
4424	SALVIA SCLAREA	A, E, H	
4425	SAMBUCUS CANADENSIS	A, H	
4426	SAMBUCUS EBULUS	A, H	
4427	SAMBUCUS NIGRA	A, E, H	
4428	SANDALWOOD OIL EAST INDIAN	A, E, H	
4429	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4430	SANICULA EUROPAEA	A, H	
4431	SANTALUM ALBUM	A, E, H	
4432	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.
4433	SAPINDUS MUKOROSI	A, H	
4434	SAPONARIA OFFICINALIS	A, H	
4435	SAPOSHNIKOVIA DIVARICATA	A, H	
4436	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%.
4437	SARGASSUM FUSIFORME	A, H	Iodine is a mandatory component of Sargassum fusiforme.

			<p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
4438	SARGASSUM SILIQUASTRUM	A, H	<p>Iodine is a mandatory component of Sargassum siliquastrum.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
4439	SASSAFRAS ALBIDUM	A, H	<p>Safrole is a mandatory component of Sassafras albidum.</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>
4440	SATUREIA HORTENSIS	A, H	
4441	SATUREIA MONTANA	A, H	
4442	SAUROPUS SPATULIFOLIUS	A, H	
4443	SAURURUS CHINENSIS	A, H	
4444	SAUSSUREA COSTUS	A, H	
4445	SAVORY OIL SUMMER	A, H	
4446	SAXIFRAGA GRANULATA	A, E, H	
4447	SAXIFRAGA STOLONIFERA	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 not be more than 0.0816%.</p>

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4448	SCAPHIUM SCAPHIGERUM	A, H	
4449	SCHEFFLERA HEPTAPHYLLA	A, H	
4450	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4451	SCHINUS MOLLE	A, H	
4452	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%.
4453	SCHISANDRA CHINENSIS	A, E, H	
4454	SCHIZONEPETA TENUIFOLIA	A, E, H	
4455	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%.
4456	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%.
4457	SCLAREOLIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4458	SCLERANTHUS ANNUUS	A, H	
4459	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.

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4460	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%.
4461	SCROPHULARIA NINGPOENSIS	A, H	
4462	SCROPHULARIA NODOSA	A, H	
4463	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4464	SCUTELLARIA BAICALENSIS	A, E, H	
4465	SCUTELLARIA BARBATA	A, H	
4466	SCUTELLARIA LATERIFLORA	A, E, H	
4467	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%.
4468	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%.
4469	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%.
4470	SECALE CEREALE	A, H	Gluten is a mandatory component of Secale cereale when the plant part is seed and the route of administration is other than topical and mucosal.
4471	SEDUM ACRE	A, H	
4472	SELAGINELLA TAMARISCINA	A, H	
4473	SELENICEREUS GRANDIFLORUS	A, E, H	

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4474	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:</p> <p>- (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>
4475	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:</p> <p>- (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>
4476	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>

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4477	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4478	SEMECARPUS ANACARDIUM	A, H	When the plant part is other than seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
4479	SEMOLINA	E	
4480	SEMPERVIVUM TECTORUM	A, H	
4481	SENEGA ROOT DRY	A, H	
4482	SENEGA ROOT POWDER	A, H	
4483	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> <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>

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			<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'.
4484	SENNA FRUIT ALEXANDRIAN DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian 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> <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</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 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'.
4485	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'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or

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			<p>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>
4486	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 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>
4487	SENNA FRUIT TINNEVELLY POWDER	A, H	When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory

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component of Senna fruit tinnevelly powder.

When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:

- (CHILD3) 'Use in children under 12 years is not recommended';
- (LAX2) 'Prolonged use may cause serious bowel problems'; and
- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).

When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:

- (LAX1) 'Drink plenty of water' (or words to that effect).

When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and
- (LAX4) 'This product may have laxative effect'.

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

- (CHILD3) 'Use in children under 12 years is not recommended';
- (LAX1) 'Drink plenty of water' (or words to that effect); and

			- (LAX2) 'Prolonged use may cause serious bowel problems'.
4488	SENNA LEAF DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna leaf 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> <ul style="list-style-type: none"> - (CHIL3) '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)]'; - (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</p>

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			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'.
4489	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> <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> <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>
4490	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 following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' [or words to that effect].</p>

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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 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	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'; 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> <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>
4492	SEPIA	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>The following warning statement is required on the medicine label:</p> <p>- (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.</p>
4493	SEQUOIA SEMPERVIRENS	A, H	
4494	SEQUOIADENDRON GIGANTEUM	A, H	
4495	SERENOA REPENS	A, H	
4496	SERINE	A, E	
4497	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.

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4498	SESAME OIL	A, E, H	
4499	SESAMUM INDICUM	A, E, H	
4500	SETARIA ITALICA	A, H	
4501	SHARK CALCIUM CHONDROITIN SULFATE	A	
4502	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)
4503	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%.
4504	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4505	SHARK SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
4506	SHARK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of Shark-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.

			<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>
4507	SHEA BUTTER	E	
4508	SHEA BUTTER ETHYL ESTERS	E	<p>Shea butter ethyl esters must:</p> <p>(a) Only be used in topical medicines for dermal application; and</p> <p>(b) Not be included in medicines intended for use on broken skin.</p> <p>The total concentration of shea butter ethyl esters in the medicine must not be more than 30%.</p>
4509	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4510	SHELLAC	E	

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4511	SHEPHERD'S PURSE HERB DRY	A, H	
4512	SHEPHERD'S PURSE HERB POWDER	A, H	
4513	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%.
4514	SIGESBECKIA ORIENTALIS	A, E, H	
4515	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%.
4516	SILICA DIMETHYL SILYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4517	SILICA SILYLATE	E	Only for use in topical medicines for dermal application.
4518	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4519	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4520	SILICONE QUATERNIUM-8	E	Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%. The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect).

4521	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:</p> <p>(a) the total concentration of silver in the medicine must not be more than 0.3%; and</p> <p>(b) the following warning statement is required on the medicine label:</p> <p>- 'Overuse may stain skin or mouth.' (or words to that effect).</p>
4522	SILVER BOROSILICATE	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 should be no more than 0.6%.</p> <p>Silver is a mandatory component of Silver borosilicate when the route of administration is topical.</p> <p>The concentration of silver in the medicine must be no more than 1%.</p>
4523	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4524	SILYBUM MARIANUM	A, E, H	
4525	SIMABA CEDRON	A, H	
4526	SIMETHICONE	E	
4527	SIMMONDSIA CHINENSIS	A, E, H	
4528	SINAPIS ALBA	A, H	<p>Allyl isothiocyanate is a mandatory component of Sinapis alba when the plant part is seed.</p> <p>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%.</p>
4529	SINAPIS ARVENSIS	A, H	

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4530	SINOMENIUM ACUTUM	A, H	
4531	SIPHONESTEGIA CHINENSIS	A, H	
4532	SIRAITIA GROSVENORII	A, E, H	
4533	SISYMBRIUM OFFICINALE	A, H	
4534	SKATOLE	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>
4535	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 - vitamin A can cause birth</p>

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			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.’
4536	SLIPPERY ELM BARK DRY	A, H	
4537	SLIPPERY ELM BARK POWDER	A, E, H	
4538	SMILAX ARISTOLOCHIIIFOLIA	A, H	
4539	SMILAX CHINA	A, H	
4540	SMILAX GLABRA	A, H	
4541	SMILAX OFFICINALIS	A, E, H	
4542	SMILAX ORNATA	A, E, H	
4543	SMOKE EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4544	SODIUM ACETATE	E	
4545	SODIUM ACETYLATED HYALURONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4546	SODIUM ACID CITRATE	A, E, H	When sodium acid citrate is used as an active ingredient, only for use in oral medicines.
4547	SODIUM ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.8%.
4548	SODIUM ACRYLATES CROSSPOLYMER-2	E	Only for use in topical medicines for dermal application and not to be included

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			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).
4549	SODIUM ACRYLOYLDIMETHYLTAURATE/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).
4550	SODIUM ALGINATE	E	
4551	SODIUM ASCORBATE	A, E, H	
4552	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%.
4553	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%.
4554	SODIUM BENZOATE	E	
4555	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
4556	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4557	SODIUM BICARBONATE	A, E	When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms. Medicines containing sodium bicarbonate for use as oral rehydration

			therapy are subject to the following conditions:
			a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts;
			b) the sodium content and total osmolality of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.'
			c) the following warning statements are required on the medicine label:
			- (UOAD) 'Use only as directed.'
			- (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice (or words to that effect).'
			- (DIAR3) 'If diarrhoea persists, seek medical advice.'
4558	SODIUM BISULFITE	E	
4559	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient. The total concentration of sodium bromide in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4560	SODIUM BUTYRATE	A, E	The route of administration for medicines that contain sodium butyrate must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 1200 mg sodium butyrate.

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			<p>The following warning statement (or words to the same effect) is required on the medicine label:</p> <p>- (ADULT) 'Adults only'.</p>
4561	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4562	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</p> <p>(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>
4563	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4564	SODIUM CARBONATE	E	<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>
4565	SODIUM CARBONATE MONOHYDRATE	E	<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>

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4566	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%.
4567	SODIUM CARRAGEENAN	E	
4568	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 than 1%.
4569	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4570	SODIUM CHLORIDE	A, E, H	
4571	SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient ingredient: a) only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye; b) the concentration in the medicine must not be more than 0.001%. When used as an active ingredient: a) the route of administration must only be oral; b) the maximum daily dose must not provide more than 1,200 mg of sodium chondroitin sulfate; c) the following statements must be included on the medicine label: - (ADULT) 'Adults only' (or words to that effect); - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).

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4572	SODIUM CITRATE	A, E	When for use as an active ingredient, only for oral use.
4573	SODIUM CITRATE DIHYDRATE	A, E	When for use as an active ingredient, only for oral use.
4574	SODIUM COCO PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
4575	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4576	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4577	SODIUM CYCLAMATE	E	
4578	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4579	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%.
4580	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4581	SODIUM ERYTHORBATE	E	
4582	SODIUM ETHYL HYDROXYBENZOATE	E	
4583	SODIUM FLUORIDE	A, E, H	Fluoride is a mandatory component of sodium fluoride. The route of administration must be limited to dental.

			<p>The dosage form must be limited to pastes, powders and/or gels for dental hygiene.</p> <p>When used as an active ingredient, the medicine 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 medicine requires the following statements on the medicine label:</p> <p>- (DNTSW) 'Do not swallow.'</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'</p>
4584	SODIUM FUMARATE	E	
4585	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>

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			<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 for use by pregnant and lactating women'.</p>
4586	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4587	SODIUM HYDROXIDE	E	<p>The concentration of sodium hydroxide in the medicine must not be more than 5%.</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>
4588	SODIUM HYDROXYCITRATE	A	
4589	SODIUM HYDROXYETHYL ACRYLATE/ACRYLOYLDIMETHYL TAURATE 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> <p>The concentration in the medicine must be no more than 1.5%.</p>
4590	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4591	SODIUM HYPOCHLORITE	E	<p>Chlorine is a mandatory component of sodium hypochlorite.</p> <p>The concentration of chlorine in the medicine must not be more than 4%.</p>
4592	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4593	SODIUM LACTATE	E	

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4594	SODIUM LAURETH SULFATE	E	
4595	SODIUM LAUROAMPHOACETATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4596	SODIUM LAUROYL LACTYLATE	E	Sodium lauroyl lactylate must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin or in the eye. The concentration in the medicine must be no more than 0.2%.
4597	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%.
4598	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4599	SODIUM LAURYL PHOSPHATE	E	
4600	SODIUM LAURYL SULFATE	E	
4601	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4602	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4603	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%.
4604	SODIUM METABISULFITE	E	

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4605	SODIUM 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 or damaged skin.</p> <p>The concentration in the medicine must not be more than 0.1%.</p>
4606	SODIUM METHYL COCOYL TAURATE	E	<p>Only for dental use.</p> <p>The concentration in the medicine must be no more than 2%.</p>
4607	SODIUM METHYL HYDROXYBENZOATE	E	
4608	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>
4609	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</p>

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			warning statements are required on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'
4610	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%.
4611	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4612	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4613	SODIUM PANTOTHENATE	A, E, H	
4614	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4615	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

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			<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>
4616	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>
4617	SODIUM POLYACRYLATE	E	<p>Only for use in topical medicines for dermal application.</p>
4618	SODIUM POLYACRYLATE STARCH	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 not be more than 1%.</p>

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4619	SODIUM POLYMETAPHOSPHATE	E	
4620	SODIUM PROPIONATE	E	
4621	SODIUM PROPYL HYDROXYBENZOATE	E	
4622	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%.
4623	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.'
4624	SODIUM SELENATE DECAHYDRATE	A	Selenium is a mandatory component of sodium selenate decahydrate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4625	SODIUM SELENITE	A, H	Selenium is a mandatory component of Sodium selenite.

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			<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>
4626	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>
4627	SODIUM SILICATE	E	
4628	SODIUM STARCH GLYCOLLATE	E	
4629	SODIUM STARCH GLYCOLLATE TYPE A	E	
4630	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4631	SODIUM STEAROXY PG-HYDROXYETHYLCELLULOSE SULFONATE	E	<p>Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p>
4632	SODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be used in

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			<p>topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2.5%.</p>
4633	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4634	SODIUM STEARYL PHTHALAMATE	E	<p>Only for use in medicines for dermal application and not to be used in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1.5%.</p>
4635	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4636	SODIUM SULFATE	A, E, H	<p>When it is not intended to be a laxative, the following warning statement is required on the medicine label:</p> <p>- (LAX4) 'Substance may have a laxative effect'.</p>
4637	SODIUM SULFATE DECAHYDRATE	A, E, H	<p>When it is not intended to be a laxative, the following warning statement is required on the medicine label:</p> <p>- (LAX4) 'Substance may have a laxative effect'.</p>
4638	SODIUM SULFITE	E	
4639	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application.
4640	SODIUM TRIPOLYPHOSPHATE	E	<p>Only for use when the route of administration is topical for dermal application, mucous membrane (buccal mucosa) or dental.</p> <p>Not to be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p>

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4641	SOLANUM DULCAMARA	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum dulcamara.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.</p>
4642	SOLANUM FEROX	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum ferox.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.</p>
4643	SOLANUM LYCOCARPUM FRUIT EXTRACT	E	<p>Only for use in topical medicines for dermal use and not to be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.02%.</p>
4644	SOLANUM MELONGENA	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum melongena.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.</p>
4645	SOLANUM NIGRUM	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum nigrum.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.</p>
4646	SOLANUM TUBEROSUM	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum tuberosum.</p>

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			When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4647	SOLIDAGO GIGANTEA	A, H	
4648	SOLIDAGO GIGANTEA MIS	A, E, H	
4649	SOLIDAGO VIRGAUREA	A, E, H	
4650	SOLUBLE MAIZE STARCH	E	
4651	SOLUBLE POTATO STARCH	E	
4652	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4653	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4654	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4655	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%.
4656	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4657	SOPHORA FLAVESCENS	A, E, H	
4658	SOPHORA TONKINENSIS	A, H	
4659	SORBIC ACID	E	
4660	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4661	SORBITAN MONO-OLEATE	E	
4662	SORBITAN MONOLAURATE	E	
4663	SORBITAN MONOSTEARATE	E	
4664	SORBITAN OLEATE	E	
4665	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.

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			The concentration in the medicine must be no more than 10%.
4666	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%.
4667	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4668	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4669	SORBITAN STEARATE	E	
4670	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4671	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.
4672	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.
4673	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 un compounded medicine substance packed for retail sale, and must comply with an un compounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
4674	SORBUS AUCUPARIA	A, H	
4675	SORGHUM	E	
4676	SORGHUM VULGARE	A, H	
4677	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	<p>Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid.</p> <p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register before 1 March 2024; and - released for supply before 1 March 2025. <p>(a) The concentration of soy phosphatidylserine in the medicine must be no more than 15%.</p> <p>The requirement specified in paragraph (b) below applies to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. <p>(b) The maximum recommended daily dose of the medicine must not provide more than 300 mg of soy phosphatidylserine.</p>
4678	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	<p>Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder.</p> <p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is:</p>

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			<p>- listed in the Register before 1 March 2024; and</p> <p>- released for supply before 1 March 2025.</p> <p>(a) The concentration of soy phosphatidylserine in the medicine must be no more than 15%.</p> <p>The requirement specified in paragraph (b) below applies to a medicine that contains the ingredient that is:</p> <p>- listed in the Register on or after 1 March 2024; or</p> <p>- released for supply on or after 1 March 2025.</p> <p>(b) The maximum recommended daily dose of the medicine must not provide more than 300 mg of soy phosphatidylserine.</p>
4679	SOY POLYSACCHARIDE	E	
4680	SOY PROTEIN	E	
4681	SOY STEROL	E	
4682	SOYA BEAN	E	
4683	SOYA OIL	A, E, H	
4684	SOYBEAN FLOUR	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>
4685	SOYBEAN GLYCERIDES	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>
4686	SPARGANIUM STOLONIFERUM	A, H	
4687	SPARTIUM JUNCEUM	A, H	
4688	SPATHOLOBUS SUBERECTUS	A, H	
4689	SPEARMINT OIL	A, E, H	Menthol is a mandatory component of spearmint oil.

			<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> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
4690	SPEARMINT 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 1%.</p>

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			<p>Menthol is a mandatory component of spearmint 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 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>
4691	SPHINGOLIPIDS	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 0.1%.</p>

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4692	SPIGELIA ANTHELMIA	A, H	
4693	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4694	SPIKE LAVENDER OIL	A, E, H	<p>Camphor is a mandatory component of spike lavender oil.</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, the concentration of camphor must be no more than 2.5%.</p> <p>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:</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</p>

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			<p>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>
4695	SPINACH	E	
4696	SPINACIA OLERACEA	A, E, H	
4697	SPIRODELA POLYRRHIZA	A, H	
4698	SPIRULINA	E	
4699	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use as an excipient for oral routes of administration.
4700	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use as an excipient for oral routes of administration.
4701	SPRUCE 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>
4702	SQUALANE	E	Only for use in topical medicines for dermal application.
4703	SQUALENE	A, E	
4704	SQUID OIL	A	<p>Only for use in oral medicines.</p> <p>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.</p> <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.

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4705	SQUILL DRY	A, H	
4706	SQUILL INDIAN DRY	A, H	
4707	SQUILL INDIAN POWDER	A, H	
4708	SQUILL POWDER	A, H	
4709	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.'
4710	ST JOHN'S WORT HERB DRY	A, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4711	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.'
4712	STACHYS OFFICINALIS	A, E, H	
4713	STACHYS PALUSTRIS	A, H	
4714	STACHYURUS HIMALAICUS	A, H	
4715	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%.
4716	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.

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4717	STAR ANISE OIL	A, E	<p>When the total concentration of star anise oil in the medicine is more than 50%:</p> <p>(a) the nominal capacity of the container must not be more than 50 mL;</p> <p>(b) a restricted flow insert must be fitted on the container; and</p> <p>(c) the following warning statement is required on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
4718	STARCH	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>
4719	STARCH SODIUM OCTENYL SUCCINATE	E	
4720	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4721	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4722	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4723	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4724	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4725	STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 2%.</p> <p>When the medicine is intended to be used on the eye, the medicine requires</p>

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			the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4726	STEARETH-10	E	Only for use in topical medicines for dermal application.
4727	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%.
4728	STEARETH-2	E	Only for use in topical medicines for dermal application.
4729	STEARETH-20	E	Only for use in topical medicines for dermal application.
4730	STEARETH-21	E	Only for use in topical medicines for dermal application.
4731	STEARETH-5	E	Only for use in topical medicines for dermal application.
4732	STEARIC ACID	E	
4733	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%.
4734	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%.
4735	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.

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4736	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4737	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4738	STEARYL ALCOHOL	E	
4739	STEARYL BEHENATE	E	Only for use as an excipient ingredient for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 3.5% in the final formulation.
4740	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).
4741	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4742	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4743	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%.

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4744	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4745	STELLARIA CHAMAEJASME	A, H	
4746	STELLARIA DICHOTOMA	A, H	
4747	STELLARIA MEDIA	A, E, H	
4748	STEMONA JAPONICA	A, H	
4749	STEMONA SESSILIFOLIA	A, H	
4750	STENOTAPHRUM SECUNDATUM	A, H	
4751	STEPHANIA TETRANDA	A, H	
4752	STERCULIA	A, H	
4753	STERCULIA TRAGACANTHA	A, H	
4754	STERCULIA URENS	A, H	
4755	STEVIA REBAUDIANA	A, E, H	
4756	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4757	STILLINGIA SYLVATICA	A, H	
4758	STORAX PREPARED	A, E, H	
4759	STRAWBERRY	E	
4760	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%.
4761	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'.

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4762	STREPTOCOCCUS THERMOPHILUS	A	
4763	STROBILANTHES CUSIA	A, H	
4764	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%.
4765	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4766	STROPHANTHUS GRATIS	H	Only for use as an active homoeopathic ingredient.
4767	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4768	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%.
4769	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%.
4770	STYPHNOLOBIUM JAPONICUM	A, E, H	
4771	STYRALLYL PROPIONATE	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.

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			The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
4772	STYRAX BENZOIN	A, E, H	
4773	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 than 1%.
4774	STYRAX PARALLELEURUM	A, H	
4775	STYRAX TONKINENSIS	A, H	
4776	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%.
4777	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4778	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%.
4779	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4780	SUCCINIC ACID	E	
4781	SUCRALOSE	E	

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4782	SUCROSE	E	
4783	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%.
4784	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%.
4785	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%.
4786	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4787	SUCROSE LAURATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate.
4788	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.
4789	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4790	SUCROSE POLYCOTTONSEEDATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. The medicine requires the following warning statements on the medicine label:

			<p>- (EYE) 'Avoid contact with the eyes' (or words to that effect)</p> <p>- (EYE2) 'May be irritant to the eyes' (or words to that effect).</p>
4791	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>
4792	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>
4793	SUDAN III	E	<p>Permitted for use only as a colour for topical use.</p>
4794	SUGAR CANE WAX ALCOHOLS	A, H	<p>The routes of administration for medicines that contain sugar cane wax alcohols must be limited to:</p> <p>(a) topical for dermal use; and</p> <p>(b) oral.</p> <p>When for use in topical medicines, the maximum recommended daily dose of the medicine must not provide more than 12 mg of sugar cane wax alcohols.</p> <p>When for oral use:</p> <p>(a) the maximum recommended daily dose of the medicine must not provide more than:</p> <p>(i) 12 mg of sugar cane wax alcohols for individuals aged less than 18 years; and</p>

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			<p>(ii) 20 mg of sugar cane wax alcohols for individuals aged 18 years and above.</p> <p>(b) The following warning statement (or words to the same effect) is required on the medicine label:</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women'.</p> <p>(c) If the maximum recommended daily dose of the medicine contains 20 mg of sugar cane wax alcohols, the following warning statement is also required on the medicine label:</p> <p>- (ADULTS) 'Adults only'.</p>
4795	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of sugarcane.
4796	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4797	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%.
4798	SULFUR DIOXIDE	E	
4799	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4800	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%.
4801	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%.

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4802	SULISOBENZONE	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).
4803	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).
4804	SUNFLOWER OIL	A, E, H	
4805	SUNFLOWER SEED	E, H	
4806	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4807	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
4808	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.

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4809	SWEDE	E	
4810	SWEET ORANGE OIL TERPENES AND TERPENOIDS	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>
4811	SWEET POTATO	E	
4812	SWERTIA CHIRATA	A, H	
4813	SWIETENIA MAHOGANI	A, H	
4814	SYAGRUS ROMANZOFFIANA	A, E, H	
4815	SYMPHYOTRICHUM NOVI-BELGII	A, H	
4816	SYMPHYTUM OFFICINALE	H	<p>When used orally as an active homoeopathic ingredient, the concentration must be a dilution of 12X or more.</p> <p>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%.</p>
4817	SYMPLOCARPUS FOETIDUS	A, H	
4818	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4819	SYNTHETIC TERPENE RESIN	E	<p>Only for use in topical, oral or oral application medicines.</p> <p>When the route of administration is oral, the dosage form must be chewing gum.</p>
4820	SYNTHETIC WAX	E	
4821	SYRINGA RETICULATA	A, H	
4822	SYRINGA VULGARIS	A, H	
4823	SYZYGIUM AROMATICUM	A, E, H	When the plant preparation is oil or distillate and the concentration of this oil or distillate in the product is greater than

			<p>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>
4824	SYZYGIUM CUMINI	A, H	
4825	SYZYGIUM JAMBOS	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 not be more than 0.0693%.</p>
4826	TABEBUIA SERRATIFOLIA	A, E, H	
4827	TADEHAGI TRIQUETRUM	A, H	
4828	TAGETES ERECTA	A, E, H	<p>When used as an excipient ingredient, only for use in combination with other permitted ingredients as a flavour proprietary excipient formulation. The</p>

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			total flavour proprietary excipient formulation in a medicine must not be more than 5%.
4829	TAGETES MINUTA	A, E, H	
4830	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 than 1%.
4831	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4832	TALLOW	E	Only for use in topical medicines for dermal application.
4833	TALLOW GLYCERIDES	E	
4834	TAMARINDUS INDICA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4835	TAMARIX APHYLLA	A, H	
4836	TAMARIX CHINENSIS	A, H	
4837	TAMARIX GALLICA	A, H	
4838	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.
4839	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.

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4840	TANACETUM COCCINEUM SUBSP. COCCINEUM	A, H	
4841	TANACETUM PARTHENIUM	A, E, H	
4842	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%.
4843	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 than 1%.
4844	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.
4845	TANNIC ACID	E	
4846	TAPIOCA STARCH	E	
4847	TARAXACUM MONGOLICUM	A, E, H	
4848	TARAXACUM OFFICINALE	A, E, H	
4849	TARO	E	
4850	TARRAGON OIL	A, E, H	
4851	TARTARIC ACID	E	
4852	TARTRAZINE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4853	TARTRAZINE ALUMINIUM LAKE	E	Only for use as a colour.

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			Only for use in medicines for topical and oral administration.
4854	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%.
4855	TAURINE	A, E	
4856	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4857	TERMINALIA ARJUNA	A	Only for use in oral medicines. Only for use when the plant part is bark. The maximum recommended daily dose must be no more than 6 grams of Terminalia arjuna dried bark or its extract equivalents. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (CHILD2) 'Not suitable for children'.
4858	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4859	TERMINALIA CATAPPA	A, H	
4860	TERMINALIA CHEBULA	A, H	
4861	TERMINALIA FERDINANDIANA	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2024; and - released for supply before 1 March 2025. (a) Only for use when the plant part is fruit flesh, fruit flesh dry or the

			<p>preparation is as an aqueous extract of the fruit flesh.</p> <p>(b) 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>(c) When used as an excipient, the concentration in the medicine must be no more than 0.3%.</p> <p>The requirements specified in paragraphs (d) to (e) below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. <p>(d) When used as an active ingredient, the plant part must be limited to fruit flesh and seed, and the plant preparation must be limited to fresh, dry, or an aqueous extract.</p> <p>(e) When used as an excipient ingredient:</p> <ul style="list-style-type: none"> (i) the route of administration for medicines that contain <i>Terminalia ferdinandiana</i> must be limited to topical for dermal use; (ii) medicines that contain <i>Terminalia ferdinandiana</i> are not to be intended for use on damaged skin or in the eye; and (iii) the concentration of <i>Terminalia ferdinandiana</i> in the medicine must not be more than 0.3%.
4862	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 <i>Terminalia sericea</i> bark of the root is approved.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>

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4863	TERPENE RESIN	E	Terpene resin must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application.
4864	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%.
4865	TERPINEOL	E	
4866	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%.
4867	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%.
4868	TERPINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

			<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>
4869	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>
4870	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>
4871	TERT-BUTYL ALCOHOL	E	<p>Only for use in topical medicines for dermal application.</p>
4872	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>
4873	TERT-BUTYL METHYL ETHER	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>
4874	TERT-BUTYLPYRAZINE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4875	TETRACLINIS ARTICULATA	A, E, H	
4876	TETRADECYL AMINOBUTYROYLVALYLAMINOBU TYRIC 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%.
4877	TETRADIUM RUTICARPUM	A, H	When for internal use, oxedrine is a mandatory component of Tetradium ruticarpum. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4878	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%.
4879	TETRAHYDRO LINALYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4880	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%.
4881	TETRAHYDRO-6-(3-PENTENYL)-2H- PYRAN-2-ONE	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%.
4882	TETRAHYDRODIFERULOYLMETHANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4883	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 than 1%.
4884	TETRAHYDROGERANYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4885	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%.
4886	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%.

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4887	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%.
4888	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4889	TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4890	TETRAPANAX PAPYRIFER	A, H	
4891	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4892	TETRASODIUM PYROPHOSPHATE	E	
4893	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4894	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4895	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4896	THAPSIA GARGANICA	A, H	
4897	THAUMATIN	E	

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4898	THEANINE	A	<p>Only to be used in a medicine where Trans Chem Pty Ltd (Client ID 21878), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 March 2026.</p> <p>The route of administration for medicines that contain theanine must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 450 mg of theanine.</p> <p>The following warning statements (or words to the same effect) are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'.
4899	THEASPIRANE	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>
4900	THEMEDA TRIANDRA	A, H	
4901	THEOBROMA CACAO	A, E, H	<p>Caffeine is a mandatory component of Theobroma cacao.</p> <p>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%.</p> <p>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.</p>

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			<p>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%.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none">- (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.' <p>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:</p> <ul style="list-style-type: none">- (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).
4902	THEOBROMA OIL	A, E, H	
4903	THIAMINE	A, E	

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4904	THIAMINE HYDROCHLORIDE	A, E	
4905	THIAMINE NITRATE	A, E	
4906	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%.
4907	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%.
4908	THLASPI ARVENSE	A, E, H	
4909	THREONINE	A, E	
4910	THUJA OCCIDENTALIS	A, H	
4911	THUJA PLICATA	A, E, H	
4912	THYME HERB DRY	A, E, H	
4913	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).
4914	THYMOL	A, E	When used as an active ingredient, the medicine must be medicated space spray or medicated throat lozenges. When used as an excipient, only for use in medicated throat lozenges or topical medicines for dermal applications.
4915	THYMOL METHYL ETHER	E	Thymol methyl ether must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.

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			The total concentration of the flavour proprietary excipient formulation containing thymol methyl ether must not be more than 5% of the total medicine.
4916	THYMUS CAPITATUS	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4917	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4918	THYMUS MASTICHINA	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4919	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).
4920	THYMUS VULGARIS	A, E, H	When the plant preparation is oil or distillate, and the concentration of

			<p>Thymus vulgaris oil or distillate in the preparation is greater than 50%:</p> <p>(a) the nominal capacity of the container must not be more than 25 millilitres;</p> <p>(b) a restricted flow insert must be fitted on the container; and</p> <p>(c) the following warning statement is required on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
4921	THYMUS VULGARIS MIS	A, E, H	<p>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%:</p> <p>(a) the nominal capacity of the container must not be more than 25 millilitres;</p> <p>(b) a restricted flow insert must be fitted on the container; and</p> <p>(c) the following warning statement is required on the label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
4922	THYMUS ZYGIS	A, H	<p>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%:</p> <p>(a) the nominal capacity of the container must not be more than 25 millilitres;</p> <p>(b) a restricted flow insert must be fitted on the container; and</p> <p>(c) the following warning statement is required on the label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
4923	TIGER SNAKE	H	<p>Only for use as an active homoeopathic ingredient.</p>

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4924	TILACTASE	A	Must be derived from <i>Aspergillus oryzae</i> and comply with the relevant USP monograph.
4925	TILIA CORDATA	A, E, H	
4926	TILIA PLATYPHYLLOS	A, E, H	
4927	TILIA TOMENTOSA	A, H	
4928	TILIA X VULGARIS	A, E, H	
4929	TILIAINTOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4930	TIN	H	Only for use as an active homoeopathic ingredient.
4931	TINOSPORA CORDIFOLIA	A, H	
4932	TINOSPORA SINENSIS	A, H	
4933	TITANIUM DIOXIDE	A, E	For use as an active ingredient only in sunscreens for dermal application. The concentration in sunscreens must be no more than 25%. For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. Not to be included in medicines intended for use in the eye. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4934	TOCOCYSTEAMIDE	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 0.01%.
4935	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>
4936	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>
4937	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>
4938	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4939	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>
4940	TOLU BALSAM	A, E, H	

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4941	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>
4942	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 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>
4943	TOLYLALDEHYDE GLYCERYLACETAL	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>
4944	TOMATO	E	
4945	TONKA	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>
4946	TONKA BEAN EXTRACT	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>

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

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4954	TRAGACANTH	A, E	
4955	TRAMETES VERSICOLOR	A, H	
4956	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4957	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%.
4958	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.
4959	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%.
4960	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%.
4961	TRANS-2-DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

			<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>
4962	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>
4963	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 than 1%.</p>
4964	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>
4965	TRANS-2-HEXENOL	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>

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4966	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>
4967	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>
4968	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>
4969	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-octenal must not be more than 1% of the total medicine.</p>
4970	TRANS-2-UNDECENAL	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>
4971	TRANS-3-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>

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4972	TRANS-4-DECENAL	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>
4973	TRANS-8-(1-METHYLETHYL)-1-OXASPIRO(4.5)DECAN-2-ONE	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>
4974	TRANS-ETHYL 2-OCTENOATE	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>
4975	TRANS-METHYL-2-HEXENOATE	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>
4976	TREACLE	E	<p>When for oral or sublingual use, sucrose is a mandatory component of treacle.</p>
4977	TREEMOSS ABSOLUTE	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 treemoss absolute must be no more than 0.02%.</p> <p>When for dermal use or use on the hair the concentration of treemoss absolute must be no more than 0.1%</p>

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			The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
4978	TREFRIW WELLS MINERAL WATER	A	<p>When for internal use, iron is a mandatory component of Trefriw Wells mineral water.</p> <p>Solid dosage forms containing more than 5 milligrams of elemental iron in each dosage unit are required to have a child resistant closure.</p> <p>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.</p> <p>Only able to be used when presented in single use sachets for therapeutic use as an iron supplement.</p>
4979	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.
4980	TREMELLA FUCIFORMIS	A, H	
4981	TRIACETIN	E	
4982	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4983	TRIADICA SEBIFERA	A, H	
4984	TRIBASIC POTASSIUM PHOSPHATE	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 tribasic potassium phosphate.</p> <p>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.</p> <p>When used in a liquid or a semi-solid medicine containing this ingredient, the</p>

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			pH of the medicine must be no more than 11.5.
4985	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.
4986	TRIBEHENIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4987	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%.
4988	TRIBULUS TERRESTRIS	A, E, H	
4989	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%.
4990	TRICALCIUM PHOSPHATE	E	
4991	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%.
4992	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%.

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4993	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4994	TRICHLOROMETHYLPHENYLCARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4995	TRICHODERMA VIRIDE	A, E, H	
4996	TRICHOSANTHES KIRILOWII	A, E, H	
4997	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
4998	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%.
4999	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%.
5000	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
5001	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%.

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5002	TRIDECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5003	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
5004	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%.
5005	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%.
5006	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
5007	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
5008	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%.
5009	TRIETHYL CITRATE	E	
5010	TRIETHYLENE GLYCOL	E	
5011	TRIFOLIUM PRATENSE	A, E, H	
5012	TRIFOLIUM REPENS	A, H	

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5013	TRIGONELLA FOENUM-GRAECUM	A, E, H	
5014	TRIHYDROXPALMITAMIDOHYDR OXYPROPYL 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%.
5015	TRIHYROXYSTEARIN	E	Only for use in topical medicines for dermal application.
5016	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
5017	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%.
5018	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%.
5019	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
5020	TRILAURIN	E	Only for use in topical medicines for dermal application.
5021	TRILISA ODORATISSIMA	A, H	
5022	TRILLIUM ERECTUM	A, H	
5023	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%.
5024	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%.
5025	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%.
5026	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%.
5027	TRIMETHYLBENZENEPROPANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5028	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%.
5029	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5030	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%.

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5031	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5032	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%.
5033	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%.
5034	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%.
5035	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%.
5036	TRIOSTEUM PERFOLIATUM	A, H	
5037	TRIOXAUNDECANEDIOIC ACID	E	
5038	TRYPEPTIDE-1	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
5039	TRIS-BIPHENYL TRIAZINE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%.

			<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).
5040	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>
5041	TRISODIUM EDETATE	E	<p>Only for use in topical medicines for dermal application.</p>
5042	TRISODIUM ETHYLENEDIAMINE DISUCCINATE	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>
5043	TRISODIUM NTA	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 0.005%.</p>
5044	TRISTEARIN	E	
5045	TRITICUM AESTIVUM	A, E, H	<p>Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal.</p>
5046	TRITICUM DURUM	A, E, H	<p>Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal.</p>

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5047	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%.
5048	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5049	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
5050	TROLAMINE SALICYLATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 12%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
5051	TROLLIUS CHINENSIS	A, H	
5052	TROMETAMOL	E	
5053	TROMETAMOL HYDROCHLORIDE	E	
5054	TROPAEOLUM MAJUS	A, E, H	
5055	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5056	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%.

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5057	TSUGA CANADENSIS	A, H	
5058	TULIPA EDULIS	A, H	Colchicine is a mandatory component of <i>Tulipa edulis</i> . The concentration of colchicine in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
5059	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5060	TURNERA DIFFUSA	A, E, H	Beta-arbutin is a mandatory component of <i>Turnera diffusa</i> . 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%.
5061	TURNIP	E	
5062	TURPENTINE OIL	A, E	Only permitted for use when turpentine oil is derived from sources other than mineral turpentine. The concentration in the medicine must not be more than 25%.
5063	TYPHA ANGUSTIFOLIA	A, H	
5064	TYPHA LATIFOLIA	A, H	

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5065	TYPHONIUM GIGANTEUM	A, H
5066	TYROSINE	A, E