

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

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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
3638	P-ALPHA-DIMETHYL STYRENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3639	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>
3640	PADIMATE O	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 8%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p>

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			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3641	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%.
3642	PAEONIA LACTIFLORA	A, E, H	
3643	PAEONIA OBOVATA	A, H	
3644	PAEONIA SUFFRUTICOSA	A, E, H	
3645	PAEONIA VEITCHII	A, H	
3646	PALIURUS SPINA-CHRISTI	A, H	
3647	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3648	PALM FRUIT OIL	A, E, H	
3649	PALM GLYCERIDES	E	
3650	PALM KERNEL OIL	A, E, H	
3651	PALM TOCOTRIENOLS COMPLEX	A, H	
3652	PALMARIA PALMATA	A, H	
3653	PALMAROSA OIL	A, E, H	
3654	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.'

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			- (21DAYS) 'Not to be used for more than 21 consecutive days.'
3655	PALMITIC ACID	E	
3656	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3657	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%.
3658	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%
3659	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%.
3660	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%.
3661	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.

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			The concentration in the medicine must be no more than 0.001%.
3662	PANAX GINSENG	A, E, H	
3663	PANAX JAPONICUS	A, H	
3664	PANAX NOTOGINSENG	A, H	
3665	PANAX PSEUDOGINSENG	A, H	
3666	PANAX QUINQUEFOLIUS	A, H	
3667	PANICUM MILIACEUM	A, H	
3668	PANTETHINE	E	Only for use in topical medicines for dermal application.
3669	PANTHENOL	A, E	
3670	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3671	PANTOLACTONE	E	
3672	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3673	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%.
3674	PAPAIN	A, E	
3675	PAPER	E	Only for use in topical medicines for dermal application.
3676	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

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			medicine must be no more than 5%.
3677	PARA-CRESOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3678	PARA-CRESYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3679	PARA-CRESYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3680	PARA-CRESYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3681	PARA-CYMENE	E	Permitted for use only in combination with other

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			permitted ingredients 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%.
3682	PARA-ETHOXYBENZALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3683	PARA-ETHYL CRESOXYACETATE	E	Para-ethyl cresoxyacetate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing para-ethyl cresoxyacetate must not be more than 1% of the total medicine.
3684	PARA-ETHYLPHENOL	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The maximum recommended daily dose must contain no more than 0.12 mg of para-ethylphenol. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
3685	PARA-HYDROXY BENZALACETONE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3686	PARA-HYDROXYBENZOIC ACID	E	
3687	PARA-MENTHA-8-THIOL-3-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3688	PARA-METHYL ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3689	PARA-METHYL ANISOLE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3690	PARA-METHYL DIMETHYLBENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3691	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>
3692	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>
3693	PARA-TERT-BUTYLPHENYL-ALPHA-METHYLHYDROCINNAMIC ALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3694	PARA-TOLUALDEHYDE	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>
3695	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>
3696	PARAMERIA LAEVIGATA	A, H	
3697	PARIETARIA JUDAICA	A, H	
3698	PARIS POLYPHYLLA	A, H	
3699	PARIS QUADRIFOLIA	A, H	
3700	PARSLEY HERB DRY	A, E, H	<p>The requirements specified 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 2025; or - released for supply on or after 1 March 2026. <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) ‘Do not use if pregnant or likely to become pregnant.’ <p>unless when:</p> <ul style="list-style-type: none"> (a) parsley herb dry is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) parsley herb dry is used as an excipient in a flavour where the total concentration of flavour proprietary excipient formulations containing

			<p>parsley herb dry must not be more than 5% of the total medicine; or</p> <p>(c) parsley herb dry is used as an excipient in a fragrance where the total concentration of fragrance proprietary excipient formulations containing parsley herb dry must not be more than 1% of the total medicine.</p>
3701	PARSLEY HERB OIL	A, E, H	<p>The requirements specified 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 2025; or - released for supply on or after 1 March 2026. <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) ‘Do not use if pregnant or likely to become pregnant.’ <p>unless when:</p> <ul style="list-style-type: none"> (a) parsley herb oil is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) parsley herb oil is used as an excipient in a flavour where the total concentration of flavour proprietary excipient formulations containing parsley herb oil must not be more than 5% of the total medicine; or (c) parsley herb oil is used as an excipient in a fragrance where the total concentration of fragrance proprietary excipient formulations containing parsley herb oil must not be more than 1% of the total medicine.

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3702	PARSLEY HERB POWDER	A, E, H	<p>The requirements specified 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 2025; or- released for supply on or after 1 March 2026. <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none">- (PREGNT2) ‘Do not use if pregnant or likely to become pregnant.’ <p>unless when:</p> <ul style="list-style-type: none">(a) parsley herb powder is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or(b) parsley herb powder is used as an excipient in a flavour where the total concentration of flavour proprietary excipient formulations containing parsley herb powder must not be more than 5% of the total medicine; or(c) parsley herb powder is used as an excipient in a fragrance where the total concentration of fragrance proprietary excipient formulations containing parsley herb powder must not be more than 1% of the total medicine.
3703	PARSLEY SEED OIL	A, E, H	<p>The requirements specified 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 2025; or- released for supply on or after 1 March 2026. <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none">- (PREGNT2) ‘Do not use if pregnant or likely to become pregnant.’

			<p>unless when:</p> <p>(a) parsley seed oil is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or</p> <p>(b) parsley seed oil is used as an excipient in a flavour where the total concentration of a flavour proprietary excipient formulations containing parsley seed oil must not be more than 5% of the total medicine; or</p> <p>(c) parsley seed oil is used as an excipient in a fragrance where the total concentration of fragrance excipient formulations containing parsley seed oil must not be more than 1% of the total medicine.</p>
3704	PARTHENOCISSUS TRICUSPIDATA	A, H	
3705	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>
3706	PARTIALLY HYDROGENATED SOYA OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in the medicine must be no more than 5%.</p>
3707	PARTIALLY REFINED PORPHYRA YEZOENSIS CYTOPLASM EXTRACT	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p>

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			The concentration in the medicine must be no more than 0.00002%.
3708	PASPALUM NOTATUM	A, H	
3709	PASSIFLORA CAERULEA	A, H	
3710	PASSIFLORA EDULIS	E	
3711	PASSIFLORA HERB DRY	A, H	
3712	PASSIFLORA INCARNATA	A, E, H	
3713	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%.
3714	PATENT BLUE V	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3715	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3716	PATRINIA SCABIOSIFOLIA	A, H	
3717	PATRINIA VILLOSA	A, H	
3718	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no

more than 400 mg of total caffeine.

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

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

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

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

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

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'
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			- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
3719	PAULLINIA PINNATA	A, H	
3720	PAWPAW	E	
3721	PEA	E	
3722	PEA STARCH	E	
3723	PEACH	E	
3724	PEAR	E	
3725	PECAN	E	
3726	PECTIN	A, E	
3727	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%.
3728	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3729	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3730	PEG-12 DILAURATE	E	
3731	PEG-12 DIMETICONE/PPG-20 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.

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3732	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3733	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3734	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3735	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3736	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%.
3737	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3738	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3739	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3740	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3741	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.

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			<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).
3742	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3743	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3744	PEG-35 CASTOR OIL	E	
3745	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3746	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>
3747	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.

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3748	PEG-40 CASTOR OIL	E	
3749	PEG-40 HYDROGENATED CASTOR OIL	E	
3750	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>
3751	PEG-40 STEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
3752	PEG-45/DODECYL GLYCOL COPOLYMER	E	<p>Only for use in topical medicines for dermal application.</p>
3753	PEG-5 GLYCERYL STEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
3754	PEG-50 STEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
3755	PEG-55 PROPYLENE GLYCOL OLEATE	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 0.6%.</p>
3756	PEG-6 LAURAMIDE	E	<p>Only for use in topical medicines for dermal application.</p>

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3757	PEG-60 ALMOND 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 when used in medicines applied directly to the skin must be no more than 10%.</p> <p>The concentration when used in bath oil medicines must be no more than 30%.</p>
3758	PEG-60 GLYCERYL ISOSTEARATE	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>
3759	PEG-60 HYDROGENATED CASTOR OIL	E	<p>Only for use in topical medicines for dermal application.</p>
3760	PEG-7 COCAMIDE	E	<p>Only for use in topical medicines for dermal application.</p>
3761	PEG-7 GLYCERYL COCOATE	E	<p>Only for use in topical medicines for dermal application.</p>
3762	PEG-7 HYDROGENATED CASTOR OIL	E	<p>Only for use in topical medicines for dermal application.</p>
3763	PEG-75 LANOLIN	E	<p>Only for use in topical medicines for dermal application.</p>
3764	PEG-75 STEARATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p>

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			The concentration in the medicine must be no more than 1.5%.
3765	PEG-8 CETYL 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 0.0005%.</p>
3766	PEG-8 DILAURATE	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>
3767	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3768	PEG-8 LAURATE	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> <p>The levels of possible impurities such as ethylene oxide (and related material) must be kept below the level of detection.</p>
3769	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3770	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.

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3771	PEG-9 POLYDIMETHYLSILOXYETHYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.5%.
3772	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%.
3773	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%.
3774	PELARGONIUM GRAVEOLENS	A, E, H	
3775	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%.
3776	PELTIGERA CANINA	A, H	
3777	PENICILLIUM EXPANSUM	A, H	
3778	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%.

			<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 the medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.</p> <p>When the medicine is for a use other than topical, the maximum recommended daily dose must be no more than 50 mg of Pennyroyal Oil.</p>
3779	PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE	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 0.018%</p>
3780	PENTAERYTHRITYL TETRAISOSTEARATE	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 61%.</p>
3781	PENTAERYTHRITYL TETRALAURATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 80%.</p>
3782	PENTAMETHYLHEPTENONE	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%.
3783	PENTANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3784	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%.
3785	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%.
3786	PEPPER BLACK	E, H	
3787	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%.
3788	PEPPERMINT AMERICAN EXT.	E	Menthol is a mandatory component of peppermint american ext.

	<p>When the medicine is for topical use for dermal application:</p> <p>a) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>b) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>c) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>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:</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>e) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</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 LEAF DRY	A, E, H	Menthol is a mandatory component of peppermint leaf dry.

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When the medicine is for topical use for dermal application:

(i) the medicine must not be intended for use in the eye or on damaged skin;

(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;

(iii) the following warning statement is required on the medicine label:

- (EYE) Avoid contact with eyes (or words to that effect).

(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:

- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;

- (IRRIT) If irritation develops, discontinue use.

(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:

– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.

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

3790	PEPPERMINT LEAF POWDER	A, E, H	Menthol is a mandatory component of peppermint leaf powder.
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	<p>When the medicine is for topical use for dermal application:</p> <ul style="list-style-type: none"> (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: <ul style="list-style-type: none"> - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: <ul style="list-style-type: none"> - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: <ul style="list-style-type: none"> - (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
<p>3791 PEPPERMINT OIL A, E, H</p>	<p>Menthol is a mandatory component of peppermint oil.</p>

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When the medicine is for topical use for dermal application:

(i) the medicine must not be intended for use in the eye or on damaged skin;

(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;

(iii) the following warning statement is required on the medicine label:

- (EYE) Avoid contact with eyes (or words to that effect).

(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:

- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;

- (IRRIT) If irritation develops, discontinue use.

(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:

- (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.

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

3792

PEPPERMINT OIL TERPENELESS E

Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient

formulation or fragrance
proprietary excipient
formulation.

The total flavour proprietary excipient formulation in a medicine must be no more than 5%.

The total fragrance proprietary excipient formulation in a medicine must be no more 1%.

Menthol is a mandatory component of peppermint oil terpeneless.

When the medicine is for topical use for dermal application:

i) the medicine must not be intended for use in the eye or on damaged skin;

ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;

iii) the following warning statement is required on the medicine label:

- (EYE) Avoid contact with eyes (or words to that effect).

iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:

- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;

- (IRRIT) If irritation develops, discontinue use.

v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:

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			<p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3793	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>
3794	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3795	PERHYDRO-3,6-DIMETHYLBENZO [B] FURAN-2-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3796	PERILLA FRUTESCENS	A, E, H	
3797	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>

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3798	PERLITE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3799	PERMETHRIN	E	The total concentration of permethrin in the medicine must not be more than 2%.
3800	PERSEA AMERICANA	A, E, H	
3801	PERSIC OIL	A, E, H	Amygdalin and Hydrocyanic acid are mandatory components of Persic oil. The concentration of amygdalin in the medicine must be no more than 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
3802	PERSICARIA CHINENSIS	A, H	
3803	PERSICARIA TINCTORIA	A, H	
3804	PERU BALSAM	A, E, H	
3805	PERU BALSAM OIL	A, E, H	
3806	PETITGRAIN MANDARIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour The final concentration of the oil in the flavour does not exceed 30% If used in a flavour the total flavour concentration in a medicine must be no more than 5%
3807	PETITGRAIN OIL	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 1%.</p>
3808	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>
3809	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>
3810	PETITGRAIN 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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3811	PETROSELINUM CRISPUM	A, E, H	<p>The requirements specified 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 2025; or - released for supply on or after 1 March 2026. <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) ‘Do not use if pregnant or likely to become pregnant.’ <p>unless when:</p> <ul style="list-style-type: none"> (a) Petroselinum crispum is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) Petroselinum crispum is used as an excipient where the total concentration of flavour proprietary excipient formulations containing Petroselinum crispum must not be more than 5% of the total medicine; or (c) Petroselinum crispum is used as an excipient in a fragrance where the total concentration of fragrance proprietary excipient formulations containing Petroselinum crispum must not be more than 1% of the total medicine.
3812	PEUCEDANUM PRAERUPTORUM	A, E, H	
3813	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>
3814	PHALARIS ARUNDINACEA	A, H	

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3815	PHALARIS CANARIENSIS	A, H	
3816	PHASEOLUS COCCINEUS	A, H	
3817	PHASEOLUS VULGARIS	A, H	
3818	PELLINUS ROBINIAE	A, E, H	
3819	PHELLODENDRON AMURENSE	A, E, H	
3820	PHELLODENDRON CHINENSE	A, H	
3821	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3822	PHENETHYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3823	PHENETHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3824	PHENETHYL ALCOHOL	E	Permitted for use only: a) in topical medicines for dermal application; and b) for internal use in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.

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			The total flavour proprietary excipient formulation concentration in a medicine must be no more than 5%.
3825	PHENETHYL BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3826	PHENETHYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%
3827	PHENETHYL ISOAMYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3828	PHENETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3829	PHENETHYL ISOVALERATE	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 1%.</p>
3830	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>
3831	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>
3832	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>
3833	PHENOXYACETALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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3834	PHENOXYETHANOL	E	<p>The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register before 1 March 2025; and - released for supply before 1 March 2026. <p>(a) Only for use in topical medicines for dermal application.</p> <p>(b) The concentration of phenoxyethanol in the preparation must not exceed 15%.</p> <p>The requirements specified in paragraphs (c) to (d) 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 2025; or - released for supply on or after 1 March 2026. <p>(c) Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>(d) The concentration of phenoxyethanol in the preparation must not exceed 1%.</p>
3835	PHENOXYETHYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3836	PHENOXYETHYLPARABEN	E	<p>Only for use in topical medicines for dermal application.</p>

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3837	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3838	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3839	PHENYLACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3840	PHENYLACETALDEHYDE DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3841	PHENYLACETALDEHYDE GLYCERYLACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3842	PHENYLACETIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3843	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>
3844	PHENYLBENZIMIDAZOLE SULFONIC ACID	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 4%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p>
3845	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>

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3846	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>
3847	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 1%.</p>
3848	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>
3849	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> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3850	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</p>

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			medicine must be no more than 5%.
3851	PHENYLETHYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3852	PHENYLETHYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3853	PHENYLISOPROPYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3854	PHENYLPROPANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.16%.
3855	PHLEUM PRATENSE	A, H	Only permitted in preparations other than phleum pratense pollen extract.

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3856	PHLOXINE B	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3857	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3858	PHOENIX DACTYLIFERA	A, E, H	
3859	PHOSPHATIDYL CHOLINE	E	
3860	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%.
3861	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3862	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%.
3863	PHOTINIA SERRULATA	A, H	
3864	PHRAGMITES AUSTRALIS	A, H	
3865	PHYLLANTHUS AMARUS	A, H	
3866	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
3867	PHYLLOSTACHYS NIGRA	A, E, H	
3868	PHYSALIS ALKEKENGI	A, H	
3869	PHYSALIS PUBESCENS	A, H	
3870	PHYTANTRIOL	E	Only for use in topical medicines for dermal application.

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			The concentration in the medicine must be no more than 0.5%.
3871	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%.
3872	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3873	PHYTOMENADIONE	A, E	
3874	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%.
3875	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%.
3876	PICEA ABIES	A, H	
3877	PICEA MARIANA	A, H	
3878	PICRAMIS EXCELSA	A, E, H	
3879	PICRORRHIZA KURROA	A, E, H	
3880	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%.

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3881	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%.
3882	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%.
3883	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3884	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3885	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3886	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3887	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.
3888	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3889	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.

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3890	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.
3891	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%.
3892	PILOCARPUS MICROPHYLLUS	A, H	Pilocarpine is a mandatory component of Pilocarpus microphyllus. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3893	PILOCARPUS PINNATIFOLIUS	A, H	Pilocarpine is a mandatory component of Pilocarpus pinnatifolius. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3894	PIMENTA FRUIT OIL	A, E, H	
3895	PIMENTA LEAF OIL	A, E, H	
3896	PIMENTA OFFICINALIS	A, E, H	
3897	PIMENTA RACEMOSA	A, E, H	When the plant preparation for Pimenta racemosa is an oil and the concentration of this oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL, a restricted flow insert must be fitted on the container. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL

			<p>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'.
3898	PIMPINELLA ANISUM	A, E, H	<p>When the plant preparation for Pimpinella anisum is an oil or distillate and the concentration of this oil or distillate in the medicine is more than 50%:</p> <ul style="list-style-type: none"> a) the nominal capacity of the container must not be more than 50 millilitres; and b) a restricted flow insert must be fitted on the container; and c) the medicine requires the following warning statement on the medicine label: <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect).
3899	PIMPINELLA SAXIFRAGA	A, E, H	
3900	PINE NEEDLE OIL SCOTCH	A, E, H	
3901	PINE NEEDLE OIL TERPENELESS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3902	PINE OIL AROMATIC	A, E, H	
3903	PINE OIL PUMILIO	A, E, H	
3904	PINEAPPLE	E	

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3905	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%.
3906	PINELLIA TERNATA	A, H	
3907	PINUS CONTORTA	A, E, H	
3908	PINUS ELLIOTTII	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5% If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3909	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%.
3910	PINUS MONTICOLA	A, E, H	
3911	PINUS MUGO	A, E, H	
3912	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%.
3913	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%.

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3914	PINUS PONDEROSA	A, E, H	
3915	PINUS RADIATA	A, E, H	
3916	PINUS STROBUS	A, E, H	
3917	PINUS SYLVESTRIS	A, E, H	
3918	PINUS TABULIFORMIS	A, E, H	
3919	PINUS YUNNANENSIS	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>
3920	PIPENZOLATE BROMIDE	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>
3921	PIPER CHABA	A, E, H	
3922	PIPER CUBEBA	A, E, H	
3923	PIPER KADSURA	A, E, H	
3924	PIPER LONGUM	A, E, H	
3925	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</p>

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			<p>than 125 mg per tablet or capsule.</p> <p>Oral medicines containing more than 25 mg of kavalactones (of Piper methysticum) per dose require the following warning statement on the medicine label:</p> <p>- (PIPER) 'Not for prolonged use. If symptoms persist - seek advice from a healthcare practitioner. Not recommended for pregnant or lactating women (or words to that effect). May harm the liver'.</p> <p>The plant part must be root or rhizome.</p> <p>When for oral use, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome.</p> <p>When for topical use on the rectum, vagina or throat, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome.</p> <p>When the container type is tea bag the maximum quantity per tea bag must be no more than 3 grams of dried whole or peeled root or rhizomes.</p>
3926	PIPER NIGRUM	A, E, H	
3927	PIPER SARMENTOSUM	A, E, H	
3928	PIPERINE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary formulation.</p> <p>The total flavour proprietary formulation in a medicine must not be more than 5% and the concentration of piperine in the</p>

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			medicine must not be more than 0.15%.
3929	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%.
3930	PIPERONAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3931	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%.
3932	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application.
3933	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

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			1% in wash-on/wash-off medicines and 0.5% in leave-on medicines.
3934	PISCIDIA PISCIPULA	A, E, H	
3935	PISTACIA LENTISCUS	A, E, H	
3936	PISUM SATIVUM	A, E, H	
3937	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3938	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).
3939	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).
3940	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).
3941	PLANTAGO LANCEOLATA	A, E, H	The medicine requires the following warning statement on the medicine label: - (CHILD5) 'Use in children under 3 years is not recommended'

			When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3942	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).
3943	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).
3944	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).
3945	PLATANUS OCCIDENTALIS	A, E, H	
3946	PLATANUS RACEMOSA	A, H	
3947	PLATANUS × HISPANICA	A, H	
3948	PLATYCODON GRANDIFLORUS	A, E, H	
3949	PLECTRANTHUS BARBATUS	A, E, H	
3950	PLICATONE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3951	PLUM	E	
3952	PLUMBAGO EUROPAEA	A, H	
3953	PLUMERIA ALBA	A, E, H	
3954	PLUMERIA RUBRA	A, E, H	
3955	POA NEMORALIS	A, H	
3956	POA PRATENSIS	A, H	
3957	PODOPHYLLUM PELTATUM	A, H	Podophyllin and podophyllotoxin are mandatory components of Podophyllum peltatum. The concentration of podophyllin in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%. The concentration of podophyllotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3958	POGOSTEMON CABLIN	A, E, H	
3959	POLACRILIN	E	
3960	POLACRILIN POTASSIUM	E	
3961	POLAPREZINC	A	Only for use in oral medicines. Zinc is a mandatory component of Polaprezinc. The maximum recommended daily dose must be no more than 34 milligrams of zinc sourced from polaprezinc. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the

			<p>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>
3962	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>
3963	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 <i>Aspergillus niger</i>;</p>

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			<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 <i>Aspergillus niger</i> is only permitted for use in topical medicines for dermal application.</p>
3964	POLLACK-LIVER OIL	A, E	<p>Colecalciferol and Vitamin A are mandatory components of Pollack-liver oil.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements</p>

			<p>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> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p>
3965	POLLEN	E	<p>The medicine requires the following warning statement on the medicine label:</p> <p>- (POLLEN) ‘This medicine can cause severe allergic reactions’ (or words to that effect).</p>
3966	POLOXAMER	E	<p>Only for use in topical medicines for dermal application.</p>
3967	POLOXAMINE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3968	POLY C10-30 ALKYL ACRYLATE	E	<p>Only for use in topical medicines for dermal application and not to be</p>

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			<p>included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p>
3969	POLYACRYLAMIDE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Acrylamide is a mandatory component of Polyacrylamide.</p> <p>The concentration of Acrylamide in the medicine must be no more than 0.01%.</p>
3970	POLYACRYLATE CROSSPOLYMER-6	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 2%.</p>
3971	POLYACRYLATE DISPERSION (30 PER CENT)	E	<p>Methyl methacrylate is a mandatory component of polyacrylate dispersion (30 per cent).</p> <p>The total concentration of methyl methacrylate as residual monomer in the medicine must not be more than 1%.</p> <p>The route of administration for medicines that contain polyacrylate dispersion (30 per cent) must be limited to oral use.</p> <p>Polyacrylate dispersion (30 per cent) is not permitted for use in children under the age of 4 years.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>a) 1.33 grams of polyacrylate dispersion (30 per cent) to</p>

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			<p>individuals aged 4 to 17 years (inclusive); and</p> <p>b) 4.67 grams of polyacrylate dispersion (30 per cent) to individuals aged 18 years and above.</p>
3972	POLYACRYLATE-1 CROSSPOLYMER	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 0.4%.</p>
3973	POLYACRYLIC ACID	E	
3974	POLYAMINO SUGAR CONDENSATE	E	<p>Only for use in topical medicines for dermal application.</p>
3975	POLYAMINOPROPYL BIGUANIDE	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 0.3%.</p>
3976	POLYBUTADIENE	E	<p>Only for use as part of an adhesive in topical medicines for dermal application.</p>
3977	POLYBUTENE	E	<p>Only for use in topical medicines for dermal application.</p>
3978	POLYBUTYLENE GLYCOL/PPG- 9/1 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 2%.</p>

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3979	POLYCAPROLACTONE	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>
3980	POLYDECENE	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>
3981	POLYDEXTROSE	E	
3982	POLYDIETHYLSILOXANE	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 5%.</p>
3983	POLYDIMETHYL SILOXANE	E	<p>Permitted for use only in combination with other permitted ingredients as a printing ink.</p> <p>If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%</p>
3984	POLYESTER-10	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>

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3985	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%.
3986	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%.
3987	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%.
3988	POLYETHYLENE	E	
3989	POLYGALA CHINENSIS	A, H	
3990	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.
3991	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
3992	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
3993	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.

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			The concentration in the medicine must be no more than 1.5%.
3994	POLYGLYCERYL-2 CAPRATE	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 not be more than 0.5%.</p>
3995	POLYGLYCERYL-2 DIISOSTEARATE	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 3.0%.</p>
3996	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 5%.</p>
3997	POLYGLYCERYL-2 DISTEARATE	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 3%.</p>
3998	POLYGLYCERYL-2 ISOSTEARATE	E	<p>Polyglyceryl-2 isostearate 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 or in the eye.</p>

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			The concentration in the medicine must be no more than 2.5%.
3999	POLYGLYCERYL-2 TRIISOSTEARATE	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>When the concentration of polyglyceryl-2 triisostearate is greater than 3%, the medicine must not be intended for use on damaged skin.</p> <p>The concentration in the medicine must not be more than 5%.</p>
4000	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
4001	POLYGLYCERYL-3 BEESWAX	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 0.5%.</p>
4002	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4003	POLYGLYCERYL-3 DISTEARATE	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>

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4004	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%.
4005	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%.
4006	POLYGLYCERYL-3 POLYRICINOLEATE	E	
4007	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIME R DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4008	POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROX YSTEARATE/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%.
4009	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%.

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4010	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
4011	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%.
4012	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
4013	POLYGONATUM MULTIFLORUM	A, H	
4014	POLYGONATUM OFFICINALE	A, H	
4015	POLYGONATUM SIBIRICUM	A, E, H	
4016	POLYGONUM AVICULARE	A, E, H	When used as an excipient, the medicine is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. When used as an excipient, the concentration in the medicine must be no more than 0.16%.
4017	POLYGONUM BISTORTA	A, H	
4018	POLYGONUM ODORATUM	A, H	
4019	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
4020	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

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			to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopoeia National Formulary, as in force or existing from time to time.
4021	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
4022	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%.
4023	POLYMETHACRYLIC ACID	E	
4024	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%.
4025	POLYMETHYLSILSESQUIOXAN E	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4026	POLYPORUS UMBELLATUS	A, H	
4027	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.

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4028	POLYPROPYLENE GLYCOL	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
4029	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
4030	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4031	POLYQUATERNIUM-22	E	<p>Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 2%.</p>
4032	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
4033	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
4034	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.

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			The concentration in the medicine must be no more than 2.5%.
4035	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%.
4036	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%.
4037	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%.
4038	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
4039	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%
4040	POLYSILICONE-14	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration of Polysilicone-14 must be no more than 1%.
4041	POLYSILICONE-15	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4042	POLYSILICONE-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.13%.
4043	POLYSORBATE 20	E	
4044	POLYSORBATE 40	E	
4045	POLYSORBATE 60	E	
4046	POLYSORBATE 65	E	
4047	POLYSORBATE 80	E	
4048	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4049	POLYSTYRENE	E	Only for use as part of an adhesive in topical medicines for dermal application.

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4050	POLYTEF	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4051	POLYURETHANE-34	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% in spray applications and 6% in non-spray applications.
4052	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%.
4053	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4054	POLYVINYL ACETATE PHTHALATE	E	
4055	POLYVINYL ALCOHOL	E	
4056	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4057	POMEGRANATE	E	
4058	PONCEAU SX	E	Permitted for use only as a colour for topical use.

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4059	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.
4060	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%.
4061	PONTEDERIA CRASSIPES	A, H	
4062	POPPY SEED	E, H	
4063	POPPY SEED OIL	E, H	
4064	POPULUS ALBA	A, H	
4065	POPULUS BALSAMIIFERA	A, E, H	
4066	POPULUS CANDICANS	A, H	
4067	POPULUS DELTOIDES	A, H	
4068	POPULUS NIGRA	A, H	
4069	POPULUS TREMULA	A, H	
4070	POPULUS TREMULOIDES	A, H	
4071	PORCINE	H	Only for use as an active homoeopathic ingredient.
4072	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%.
4073	PORTULACA OLERACEA	A, E, H	
4074	POTABLE WATER	E	
4075	POTASSIUM ACETATE	E	
4076	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.

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4077	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4078	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4079	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4080	POTASSIUM ASPARTATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium aspartate.
4081	POTASSIUM ASPARTATE DIHYDRATE	A, E, H	If used as an active ingredient and the preparation is intended as a mineral supplementation, potassium is a mandatory component of Potassium aspartate dihydrate. The percentage of potassium from potassium aspartate dihydrate should be calculated based on the molecular weight of potassium aspartate dihydrate.
4082	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.
4083	POTASSIUM BICARBONATE	E	

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4084	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%.
4085	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.
4086	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4087	POTASSIUM CHLORIDE	A, E, H	When for oral use: (a) potassium is a mandatory component of potassium chloride; (b) the medicine requires the following warning statement on the medicine label: - (POTAS1) 'If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and (c) except when the medicine is for use as oral rehydration therapy, the amount of potassium chloride per dosage unit must not be more than 550 mg. Medicines containing potassium chloride for use as oral rehydration therapy, are subject to the following conditions: (a) the medicine complies with the requirements specified in the British Pharmacopoeia, as

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			<p>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>
4088	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.
4089	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>
4090	POTASSIUM COCOYL HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.
4091	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4092	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.
4093	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.
4094	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.
4095	POTASSIUM HYDROXYCITRATE	A, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. When for oral use, the following warning statement is required on the medicine label: ‘In very rare cases, potassium hydroxycitrate may harm the liver. Stop use and see a doctor

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			<p>if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.’</p> <p>Medicines containing potassium hydroxycitrate must not be directed for use in children, or in pregnant or lactating women.</p>
4096	POTASSIUM IODATE	A, H	<p>Iodine is a mandatory component of potassium iodate.</p> <p>The percentage of iodine from potassium iodate should be calculated based on the molecular weight of potassium iodate.</p> <p>When for use in adults, the medicine must contain a daily dose of no more than 505 micrograms of potassium iodate.</p> <p>When for use in children aged 1-3 years, the medicine must contain a daily dose of no more than 337 micrograms of potassium iodate.</p>
4097	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 contain less than 300 micrograms of iodine.</p> <p>When for external use, the concentration of iodine in the medicine (excluding salt derivatives or iodophors) must not exceed 2.5%.</p>

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4098	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>
4099	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>
4100	POTASSIUM NITRATE	A, H	<p>Only for dental use.</p> <p>The concentration in the medicine must be no more than 5%.</p>
4101	POTASSIUM OROTATE	A, E, H	<p>When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium orotate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
4102	POTASSIUM PYROPHOSPHATE	E	<p>Only for oral application, dental or topical use.</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 3%.</p>

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4103	POTASSIUM SORBATE	E	
4104	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%.
4105	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4106	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.
4107	POTATO STARCH	E	
4108	POTENTILLA ANSERINA	A, H	
4109	POTENTILLA CHINENSIS	A, H	
4110	POTENTILLA DISCOLOR	A, H	
4111	POTENTILLA ERECTA	A, E, H	
4112	POTENTILLA REPTANS	A, H	
4113	POTERIUM OFFICINALE	A, E, H	
4114	POTERIUM SANGUISORBA	A, H	
4115	POVIDONE	E	
4116	POWDERED CELLULOSE	E	
4117	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.

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			The concentration in the medicine must be no more than 5%.
4118	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%.
4119	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%.
4120	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%.
4121	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%.
4122	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.

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4123	PPG-2 MYRISTYL ETHER PROPIONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4124	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4125	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%.
4126	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4127	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%.
4128	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4129	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4130	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.

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4131	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%.
4132	PREGELATINISED MAIZE STARCH	E	
4133	PREGELATINISED POTATO STARCH	E	
4134	PREGELATINISED RICE STARCH	E	
4135	PREGELATINISED STARCH	E	
4136	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4137	PRENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4138	PRICKLY ASH BARK DRY	A, H	
4139	PRICKLY ASH BARK POWDER	A, H	
4140	PRIMULA VERIS	A, E, H	
4141	PRIMULA VULGARIS	A, E, H	
4142	PRINSEPIA UNIFLORA	A, H	
4143	PROBOSCIDEA PARVIFLORA	A, H	
4144	PROGESTERONE	H	Only for use as an active homoeopathic ingredient. The total concentration of progesterone in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.

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4145	PROLINE	A, E	
4146	PROPAN-1-OL	E	<p>Only for use in:</p> <ul style="list-style-type: none"> - topical medicines for dermal application; or - in combination with other permitted ingredients as a flavour proprietary excipient formulation. <p>The concentration of propan-1-ol in the medicine must not be more than 18%.</p> <p>When used in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation, the total flavour proprietary excipient formulation in a medicine must not be more than 5%.</p>
4147	PROPANE	E	<p>Only for use as an excipient propellant ingredient.</p>
4148	PROPANEDIOL	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 10%.</p>
4149	PROPENYL GUAETHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4150	PROPIONALDEHYDE	E	<p>Permitted for use only in combination with other</p>

			permitted ingredients 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%.
4151	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%.
4152	PROPIONYLLEVOCARNITINE HYDROCHLORIDE	A, H	
4153	PROPOLIS	A, E	Lead is a mandatory component of Propolis. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'

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4154	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>
4155	PROPOLIS DRY EXTRACT	A, E	<p>Lead is a mandatory component of Propolis dry extract.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>

4156	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>
4157	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>

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4158	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>
4159	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>
4160	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>
4161	PROPYL GALLATE	E	
4162	PROPYL HYDROXYBENZOATE	E	
4163	PROPYLENE CARBONATE	E	<p>Only for use in topical medicines for dermal application.</p>

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4164	PROPYLENE GLYCOL	E	
4165	PROPYLENE GLYCOL ALGINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4166	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%.
4167	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%.
4168	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4169	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4170	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4171	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.

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			The concentration in the medicine must be no more than 1%.
4172	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4173	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4174	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4175	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4176	PROSOPIS JULIFLORA	A, H	
4177	PROTEASE	A	Must be derived from <i>Aspergillus oryzae</i> or <i>Aspergillus niger</i> .
4178	PROTEIN HYDROLYSATE	E	
4179	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%.
4180	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%.
4181	PRUNELLA VULGARIS	A, H	

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4182	PRUNUS AFRICANA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus africana.</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 ARMENIACA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus armeniaca and must be declared in the application.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4184	PRUNUS 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>
4185	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</p>

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			1 microgram/kg or 1 microgram/L or 0.0000001%.
4186	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>
4187	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>
4188	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>

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4189	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>
4190	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>
4191	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>
4192	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</p>

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			1 microgram/kg or 1 microgram/L or 0.0000001%.
4193	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>
4194	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>
4195	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>
4196	PRUNUS SPINOSA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than</p>

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			1 microgram/kg or 1 microgram/L or 0.0000001%.
4197	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4198	PSEUDOCYDONIA SINENSIS	A, H	
4199	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4200	PSEUDOTSUGA MENZIESII	A, H	
4201	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4202	PSIDIUM GUAJAVA	A, E, H	
4203	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4204	PSYLLIUM HUSK DRY	A, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4205	PSYLLIUM HUSK POWDER	A, E, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4206	PSYLLIUM SEED DRY	A, E, H	When a dose for children is stated the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4207	PTELEA TRIFOLIATA	A, H	
4208	PTEROCARPUS MARSUPIUM	A, H	

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4209	PTEROCARPUS SANTALINUS	A, E, H	
4210	PUERARIA LOBATA	A, E, H	
4211	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4212	PULLULAN	E	
4213	PUMICE	E	
4214	PUMPKIN	E	
4215	PUMPKIN SEED OIL	E, H	
4216	PUNICA GRANATUM	A, E, H	
4217	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4218	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).
4219	PURIFIED SILICEOUS EARTH	E, H	
4220	PURIFIED TALC	E	
4221	PURIFIED WATER	E	
4222	PVM/MA COPOLYMER	E	
4223	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4224	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4225	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4226	PYRETHRINS	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.

			<p>The medicine requires the following warning statement on the medicine label:</p> <p>- (PYRTH3) 'Contains pyrethrins [insert quantity]' (or words to that effect).</p>
4227	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> <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>

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4228	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> <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>
4229	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</p>

			<p>the molecular weight of pyridoxine hydrochloride.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive);</p> <p>(ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive);</p> <p>(iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive);</p> <p>(iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and</p> <p>(v) 100 mg of pyridoxine for individuals aged 19 years and older.</p> <p>If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label:</p> <p>- (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'</p>
4230	PYROGLUTAMIC ACID	E	
4231	PYROLA DECORATA	A, H	
4232	PYROLIGNEOUS ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4233	PYRROSIA LINGUA	A, H	
4234	PYRROSIA PETIOLOSA	A, H	

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4235	PYRROSIA SHEARERI	A, H	
4236	PYRUS COMMUNIS	A, E, H	<p>Beta-arbutin is a mandatory component of <i>Pyrus communis</i>.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
4237	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</p>

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			must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4238	PYRUVIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4239	QUASSIA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4240	QUASSIA AMARA	A, E, H	
4241	QUASSIA WOOD JAMAICAN DRY	A, H	
4242	QUASSIA WOOD JAMAICAN POWDER	A, H	
4243	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4244	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4245	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4246	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%.

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			Not be used in medicines in which N-nitroso compounds may be formed.
4247	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%.
4248	QUERCETIN	A	
4249	QUERCETIN DIHYDRATE	A	
4250	QUERCUS ACUTISSIMA	A, H	
4251	QUERCUS ALBA	A, E, H	
4252	QUERCUS PALUSTRIS	A, H	
4253	QUERCUS ROBUR	A, H	
4254	QUERCUS RUBRA	A, H	
4255	QUERCUS VIRGINIANA	A, H	
4256	QUILLAIA DRY	A, H	
4257	QUILLAIA POWDER	A, E, H	
4258	QUILLAIA SAPONARIA	A, H	
4259	QUINCE	E	
4260	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.
4261	QUININE SULFATE DIHYDRATE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of quinine sulfate dihydrate. The maximum recommended daily dose must be no more than 50 mg of quinine.
4262	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.

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4263	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4264	QUISQUALIS INDICA	A, H	
4265	R-ALPHA LIPOIC ACID	A	
4266	RACEMENTHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4267	RACEMIC CAMPHOR	E, H	Only for use as an active homoeopathic or excipient ingredient. In solid and semi solid preparations, the concentration of camphor must not be more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must not be more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and - (BABY4) 'Do not apply to infants under 12 months of age except on the advice of a

doctor or pharmacist' (or words to that effect).

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect);
 - (NTAKEN) 'Not to be taken';
- and
- (BABY4) 'Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist' (or words to that effect).

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect);
 - (NTAKEN) 'Not to be taken';
- and
- (BABY4) 'Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist' (or words to that effect).

If the concentration of camphor is more than 2.5%, the nominal capacity of the container must not be more than 25 millilitres.

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4268	RAISIN JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4269	RANUNCULUS BULBOSUS	A, H	
4270	RANUNCULUS FICARIA	A, H	
4271	RANUNCULUS TERNATUS	A, H	
4272	RAPE SEED OIL	A, E, H	Allyl isothiocyanate is a mandatory component of rape seed oil when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
4273	RAPHANUS SATIVUS	A, E, H	When used as an excipient, the plant preparation must be limited to fresh, dry, powder, oil, fresh juice, dry juice, or concentrated juice.
4274	RASPBERRY	E	
4275	RASPBERRY BRANDY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4276	RASPBERRY DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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4277	RASPBERRY FRUIT EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4278	RASPBERRY JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4279	RAUWOLFIA SERPENTINA	A, H	The concentration of equivalent dry Rauwolfia serpentina in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4280	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%.
4281	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%.
4282	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%.
4283	RED 27 ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to

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			topical and oral routes of administration. The concentration in the medicine must be no more than 0.5%.
4284	RED ANT	H	Only for use as an active homoeopathic ingredient.
4285	RED CLOVER FLOWER DRY	A, H	
4286	RED CLOVER FLOWER POWDER	A, H	
4287	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4288	RED DEER	A	
4289	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4290	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4291	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4292	REFINED BUGLOSSOIDES ARVENSIS SEED OIL	A	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. Stearidonic acid is a mandatory component of refined Buglossoides arvensis seed oil. The route of administration for medicines that contain refined Buglossoides arvensis seed oil must be limited to oral. The maximum recommended daily dose of the medicine

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			<p>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>
4293	REHMANNIA GLUTINOSA	A, E, H	
4294	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>
4295	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>
4296	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>
4297	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>

			<p>- (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).';</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)'; and</p> <p>- (CHILD2) 'Not suitable for children'.</p>
4298	RETINOL	A, E	<p>Vitamin A is a mandatory component of retinol.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this</p>

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			<p>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>
4299	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</p>

			for women and 900 micrograms retinol equivalents for men.’
4300	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> <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.’

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4301	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4302	RHAMNOSE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4303	RHAMNUS CATHARTICA	A, H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect).

			<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'.
4304	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

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vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).

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

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

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

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and

- (LAX4) 'This product may have laxative effect'.

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

- (CHILD3) 'Use in children under 12 years is not recommended';

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

- (LAX2) 'Prolonged use may cause serious bowel problems'.

4305	RHATANY ROOT DRY	A, H	
4306	RHATANY ROOT POWDER	A, H	
4307	RHEUM OFFICINALE	A, E, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives

calculated as rhein is a mandatory component of *Rheum officinale*.

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

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

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

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

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

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

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or

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			<p>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'.
4308	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). <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>
4309	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>

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- (LAX2) 'Prolonged use may cause serious bowel problems'; and

- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).

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

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

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

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and

- (LAX4) 'This product may have laxative effect'.

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

- (CHILD3) 'Use in children under 12 years is not recommended';

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

- (LAX2) 'Prolonged use may cause serious bowel problems'.

4310

RHEUM TANGUTICUM

A, H

The plant part must not be leaf.

When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of *Rheum tanguticum*.

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

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

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

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

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

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

When used in oral medicines, if the maximum recommended

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			<p>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'.
4311	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4312	RHODINOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4313	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>
4314	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>

4315	RHODODENDRON AUREUM	A, H	
4316	RHODODENDRON FERRUGINEUM	A, H	<p>Beta-arbutin is a mandatory component of Rhododendron ferrugineum.</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>
4317	RHODODENDRON GROENLANDICUM	A, H	
4318	RHODODENDRON MOLLE	A, H	<p>The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.</p>
4319	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>

- (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'.
4320	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> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and

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- (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'.

4321	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 before taking this product' (or words to that effect).</p>
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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>
4322	RHUS AROMATICA	A, E, H	
4323	RHUS CHINENSIS	A, H	
4324	RHUS GLABRA	A, E, H	
4325	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4326	RIBES GROSSULARIA	A, E, H	
4327	RIBES NIGRUM	A, E, H	
4328	RIBOFLAVIN	A, E	
4329	RIBOFLAVIN SODIUM PHOSPHATE	A, E	

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

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4348	ROSA CYMOSA	A, E, H	
4349	ROSA EGLANTERIA	A, E, H	
4350	ROSA GALLICA	A, E, H	
4351	ROSA LAEVIGATA	A, E, H	
4352	ROSA MULTIFLORA	A, E, H	
4353	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%.
4354	ROSA RUGOSA	A, E, H	
4355	ROSA VILLOSA	A, E, H	
4356	ROSA X CENTIFOLIA	A, E, H	
4357	ROSA X DAMASCENA	A, E, H	
4358	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%.
4359	ROSE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4360	ROSE FRUIT FRESH	A, E, H	
4361	ROSE HIP	E	
4362	ROSE OIL	A, E, H	
4363	ROSE OXIDE	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>
4364	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>
4365	ROSMARINUS OFFICINALIS	A, E, H	<p>Camphor and cineole are mandatory components of Rosmarinus officinalis except when the plant preparation is an essential oil or distillate.</p> <p>In solid and semi-solid preparations, the concentration of camphor must not be more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must not be more than 2.5%.</p> <p>When the concentration of cineole in the preparation other than essential oils or distillates is more than 25%, the nominal capacity of the container must not be more than 25 millilitres.</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</p>

			<p>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, 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'.
4366	ROYAL JELLY	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by 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'.
4367	ROYAL JELLY FRESH	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh.</p>

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			<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'.
4368	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'.
4369	RUBBER NATURAL	E	<p>Only for use in topical medicines for dermal application.</p>
4370	RUBIA CORDIFOLIA	A, H	
4371	RUBIA TINCTORUM	A, H	
4372	RUBUS CHINGII	A, H	
4373	RUBUS CORCHORIFOLIUS	A, H	
4374	RUBUS COREANUS	A, E, H	
4375	RUBUS FRUTICOSUS	A, E, H	
4376	RUBUS IDAEUS	A, E, H	
4377	RUBUS OCCIDENTALIS	A, E, H	
4378	RUBUS PARVIFOLIUS	A, H	

4379	RUBUS ROSIFOLIUS	A, H	
4380	RUDBECKIA HIRTA	A, H	
4381	RUE OIL	A, E, H	<p>The requirements specified 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 2025; or - released for supply on or after 1 March 2026. <p>When used as an active ingredient:</p> <ul style="list-style-type: none"> (a) Rue oil must only be used as a homoeopathic ingredient; (b) the routes of administration for medicines that contain rue oil must be limited to: <ul style="list-style-type: none"> (i) topical for dermal use; and (ii) oral; (c) when the homoeopathic potency of the medicine containing rue oil is 12X or lower, the following warning statement is required on the medicine label: <ul style="list-style-type: none"> - (NEW) ‘Do not use if pregnant or likely to become pregnant, or during lactation.’; and (d) when the medicine is for dermal use, the following statement is required on the medicine: <ul style="list-style-type: none"> - (SENS) ‘Application to skin may increase sensitivity to sunlight’ (or words to that effect). <p>When used as an excipient ingredient:</p> <ul style="list-style-type: none"> (a) The route of administration for medicines that contain rue oil must be limited to topical; (b) rue oil must only be included in combination with other permitted ingredients as a fragrance proprietary excipient formulation;

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			(c) the total concentration of fragrance proprietary excipient formulations containing rue oil must not be more than 1% of the total medicine; and (d) the total concentration of rue oil in the medicine must not be more than 0.15%.
4382	RUM	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4383	RUMEX ACETOSA	A, H	
4384	RUMEX ACETOSELLA	A, H	
4385	RUMEX CONGLOMERATUS	A, H	
4386	RUMEX CRISPUS	A, E, H	
4387	RUMEX PULCHER	A, H	
4388	RUMEX SCUTATUS	A, H	
4389	RUSCUS ACULEATUS	A, H	
4390	RUTA GRAVEOLENS	A, E, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. When used as an active ingredient: (a) Ruta graveolens must only be used as a homoeopathic ingredient; (b) the routes of administration for medicines that contain Ruta graveolens must be limited to: (i) topical for dermal use; and (ii) oral; (c) when the homoeopathic potency of the medicine containing Ruta graveolens is 12X or lower, the following

			<p>warning statement is required on the medicine label:</p> <p>- (NEW) ‘Do not use if pregnant or likely to become pregnant, or during lactation.’; and</p> <p>(d) when the medicine is for dermal use, the following statement is required on the medicine:</p> <p>- (SENS) ‘Application to skin may increase sensitivity to sunlight’ (or words to that effect).</p> <p>When used as an excipient ingredient:</p> <p>(a) The route of administration for medicines that contain <i>Ruta graveolens</i> must be limited to topical;</p> <p>(b) <i>Ruta graveolens</i> must only be included in combination with other permitted ingredients as a fragrance proprietary excipient formulation;</p> <p>(c) the total concentration of fragrance proprietary excipient formulations containing <i>Ruta graveolens</i> must not be more than 1% of the total medicine; and</p> <p>(d) the total concentration of <i>Ruta graveolens</i> in the medicine must not be more than 0.15%.</p>
4391	RUTOSIDE	A, E	
4392	RUTOSIDE TRIHYDRATE	A, E	
4393	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4394	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.

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4395	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%.
4396	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.
4397	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%.
4398	SACCHARIDE ISOMERATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.66%.
4399	SACCHARIN	E	
4400	SACCHARIN SODIUM	E	
4401	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.

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4402	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4403	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%.
4404	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4405	SACCHARUM OFFICINARUM	A, E, H	
4406	SAFFLOWER OIL	A, E, H	
4407	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4408	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%.
4409	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%.
4410	SAGE OIL DALMATIAN	A	Thujone is a mandatory component of Sage oil dalmatian. The concentration of thujone in the medicine must be no more than 4%. When the concentration of Sage oil dalmatian in the medicine is more than 10% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert and

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			child resistant closure must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or word to that effect) - (NTAKEN) ‘Not to be taken’
4411	SAGE OIL SPANISH	A, E, H	
4412	SALICORNIA EUROPAEA EXTRACT	E	Only for use in topical medicines for dermal use and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
4413	SALICYLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4414	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4415	SALIX ALBA	A, E, H	
4416	SALIX DAPHNOIDES	A, H	
4417	SALIX DISCOLOR	A, H	
4418	SALIX FRAGILIS	A, H	
4419	SALIX NIGRA	A, H	
4420	SALIX PURPUREA	A, H	
4421	SALSOLA KALI	A, H	

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4422	SALVIA CHINENSIS	A, H	
4423	SALVIA FRUTICOSA	A, H	
4424	SALVIA HISPANICA	A, E, H	
4425	SALVIA LAVANDULAEFOLIA	A, H	
4426	SALVIA MILTIORRHIZA	A, H	
4427	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%.
4428	SALVIA SCLAREA	A, E, H	
4429	SAMBUCUS CANADENSIS	A, H	
4430	SAMBUCUS EBULUS	A, H	
4431	SAMBUCUS NIGRA	A, E, H	
4432	SANDALWOOD OIL EAST INDIAN	A, E, H	
4433	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4434	SANICULA EUROPAEA	A, H	
4435	SANTALUM ALBUM	A, E, H	
4436	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.
4437	SAPINDUS MUKOROSI	A, H	
4438	SAPONARIA OFFICINALIS	A, H	
4439	SAPOSHNIKOVIA DIVARICATA	A, H	
4440	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%.

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4441	SARGASSUM FUSIFORME	A, H	<p>Iodine is a mandatory component of Sargassum fusiforme.</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>
4442	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>
4443	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>
4444	SATUREIA HORTENSIS	A, H	
4445	SATUREIA MONTANA	A, H	
4446	SAUROPLUS SPATULIFOLIUS	A, H	
4447	SAURURUS CHINENSIS	A, H	
4448	SAUSSUREA COSTUS	A, H	
4449	SAVORY OIL SUMMER	A, H	

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4450	SAXIFRAGA GRANULATA	A, E, H	
4451	SAXIFRAGA STOLONIFERA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 0.0816%.
4452	SCAPHIUM SCAPHIGERUM	A, H	
4453	SCHEFFLERA HEPTAPHYLLA	A, H	
4454	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4455	SCHINUS MOLLE	A, H	
4456	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%.
4457	SCHISANDRA CHINENSIS	A, E, H	
4458	SCHIZONEPETA TENUIFOLIA	A, E, H	
4459	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%.
4460	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%.

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4461	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%.
4462	SCLERANTHUS ANNUUS	A, H	
4463	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4464	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%.
4465	SCROPHULARIA NINGPOENSIS	A, H	
4466	SCROPHULARIA NODOSA	A, H	
4467	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4468	SCUTELLARIA BAICALENSIS	A, E, H	
4469	SCUTELLARIA BARBATA	A, H	
4470	SCUTELLARIA LATERIFLORA	A, E, H	
4471	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%.
4472	SEC BUTYL 3-METHYLBUT-2-ENETHIOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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4473	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%.
4474	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.
4475	SEDUM ACRE	A, H	
4476	SELAGINELLA TAMARISCINA	A, H	
4477	SELENICEREUS GRANDIFLORUS	A, E, H	
4478	SELENIUM	H	Only for use as an active homoeopathic ingredient. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4479	SELENOCYSTEINE	A	Selenium is a mandatory component of Selenocysteine for oral and sublingual use. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the

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			<p>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>
4480	SELENOMETHIONINE	A	<p>Selenium is a mandatory component of Selenomethionine for oral and sublingual use.</p> <p>Oral medicines must not contain 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>
4481	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4482	SEMECARPUS ANACARDIUM	A, H	<p>When the plant part is other than seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.</p>
4483	SEMOLINA	E	
4484	SEMPERVIVUM TECTORUM	A, H	
4485	SENEGA ROOT DRY	A, H	
4486	SENEGA ROOT POWDER	A, H	
4487	SENNA ALEXANDRINA	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory</p>

component of Senna alexandrina.

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

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

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

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

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

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

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the

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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'.
4488	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> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems';</p> <p>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> <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'.
4489	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

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- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).

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

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

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

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and

- (LAX4) 'This product may have laxative effect'.

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

- (CHILD3) 'Use in children under 12 years is not recommended';

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

- (LAX2) 'Prolonged use may cause serious bowel problems'.

4490	SENNA FRUIT TINNEVELLY DRY	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory
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component of Senna fruit
tinnevelly dry.

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

- (CHILD3) 'Use in children
under 12 years is not
recommended';

- (LAX2) 'Prolonged use may
cause serious bowel problems';
and

- (LAX3) 'Do not use when
abdominal pain, nausea or
vomiting are present, or if you
develop diarrhoea. If you are
pregnant or breast feeding,
seek the advice of a healthcare
professional before taking this
product' (or words to that
effect).

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

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

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

- (LAX5) 'This product
contains [name of the herb(s)
or the chemical
component(s)']; and

- (LAX4) 'This product may
have laxative effect'.

When used in oral medicines,
if the maximum recommended
daily dose contains less than 10
mg of hydroxyanthracene
derivatives and is promoted or
marketed as laxative, the

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			<p>medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4491	SENNA FRUIT TINNEVELLY POWDER	A, H	<p>When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may 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</p>

			<p>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'.
4492	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"> - (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

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			<p>develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; - (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); <p>and</p> <ul style="list-style-type: none"> - (LAX2) 'Prolonged use may cause serious bowel problems'.
4493	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>

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

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			<p>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'.
4494	SENNA OCCIDENTALIS	A, H	<p>Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of <i>Senna occidentalis</i> 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> <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</p>

			<p>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'.
4495	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

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			<p>develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and - (LAX4) 'This product may have laxative effect'. <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4496	SEPIA	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>The following warning statement is required on the medicine label:</p>

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			- (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
4497	SEQUOIA SEMPERVIRENS	A, H	
4498	SEQUIADENDRON GIGANTEUM	A, H	
4499	SERENOA REPENS	A, H	
4500	SERINE	A, E	
4501	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4502	SESAME OIL	A, E, H	
4503	SESAMUM INDICUM	A, E, H	
4504	SETARIA ITALICA	A, H	
4505	SHARK CALCIUM CHONDROITIN SULFATE	A	
4506	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)
4507	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%.
4508	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4509	SHARK SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application;

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			<p>- not to be included in medicines intended for use in the eye; and</p> <p>- the concentration in the medicine must be no more than 0.001%.</p>
4510	SHARK-LIVER OIL	A, E	<p>Vitamin A and Colecalciferol are mandatory components of Shark-liver oil.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <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>

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			- (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.'
4511	SHEA BUTTER	E	
4512	SHEA BUTTER ETHYL ESTERS	E	Shea butter ethyl esters must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin. The total concentration of shea butter ethyl esters in the medicine must not be more than 30%.
4513	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4514	SHELLAC	E	
4515	SHEPHERD'S PURSE HERB DRY	A, H	
4516	SHEPHERD'S PURSE HERB POWDER	A, H	
4517	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%.
4518	SIGESBECKIA ORIENTALIS	A, E, H	
4519	SILICA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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4520	SILICA DIMETHYL SILYLATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 4%.</p>
4521	SILICA SILYLATE	E	<p>Only for use in topical medicines for dermal application.</p>
4522	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	<p>Only for use when the route of administration is other than inhalation.</p>
4523	SILICON DIOXIDE	A, E, H	<p>Only for use when the route of administration is other than inhalation.</p>
4524	SILICONE QUATERNIUM-8	E	<p>Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2.5%.</p> <p>The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect).</p>
4525	SILVER	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>When for external use, the total concentration of silver in the medicine must not be more than 1%.</p> <p>When for oral use: (a) the total concentration of silver in the medicine must not be more than 0.3%; and</p>

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			(b) the following warning statement is required on the medicine label: - 'Overuse may stain skin or mouth.' (or words to that effect).
4526	SILVER BOROSILICATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine should be no more than 0.6%. Silver is a mandatory component of Silver borosilicate when the route of administration is topical. The concentration of silver in the medicine must be no more than 1%.
4527	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4528	SILYBUM MARIANUM	A, E, H	
4529	SIMABA CEDRON	A, H	
4530	SIMETHICONE	E	
4531	SIMMONDSIA CHINENSIS	A, E, H	
4532	SINAPIS ALBA	A, H	Allyl isothiocyanate is a mandatory component of Sinapis alba when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
4533	SINAPIS ARVENSIS	A, H	
4534	SINOMENIUM ACUTUM	A, H	
4535	SIPHONESTEGIA CHINENSIS	A, H	
4536	SIRAITIA GROSVENORII	A, E, H	
4537	SISYMBRIUM OFFICINALE	A, H	

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4538	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 1%.</p>
4539	SKIPJACK-LIVER OIL	A, E	<p>Vitamin A and Colecalciferol are mandatory components of Skipjack-liver oil.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents</p>

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			<p>- vitamin A can cause birth defects.’ 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>
4540	SLIPPERY ELM BARK DRY	A, H	
4541	SLIPPERY ELM BARK POWDER	A, E, H	
4542	SMILAX ARISTOLOCHIIFOLIA	A, H	
4543	SMILAX CHINA	A, H	
4544	SMILAX GLABRA	A, H	
4545	SMILAX OFFICINALIS	A, E, H	
4546	SMILAX ORNATA	A, E, H	
4547	SMOKE EXTRACT	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4548	SODIUM ACETATE	E	
4549	SODIUM ACETYLATED HYALURONATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</p>
4550	SODIUM ACID CITRATE	A, E, H	<p>When sodium acid citrate is used as an active ingredient, only for use in oral medicines.</p>
4551	SODIUM ACRYLATES COPOLYMER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p>

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			The concentration in the medicine must be no more than 0.8%.
4552	SODIUM ACRYLATES CROSSPOLYMER-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.7 % (w/w).
4553	SODIUM ACRYLOYDIMETHYLTAURATE/ VP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% (w/w).
4554	SODIUM ALGINATE	E	
4555	SODIUM ASCORBATE	A, E, H	
4556	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%.
4557	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%.

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4558	SODIUM BENZOATE	E	
4559	SODIUM BETA-HYDROXY- BETA-METHYLBUTYRATE	A, H	
4560	SODIUM BETA-HYDROXY- BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4561	SODIUM BICARBONATE	A, E	<p>When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms.</p> <p>Medicines containing sodium bicarbonate for use as oral rehydration therapy are subject to the following conditions:</p> <p>a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts;</p> <p>b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.'</p> <p>c) the following warning statements are required on the medicine label:</p> <p>- (UOAD) 'Use only as directed.'</p> <p>- (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice (or words to that effect).'</p>

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			- (DIAR3) 'If diarrhoea persists, seek medical advice.'
4562	SODIUM BISULFITE	E	
4563	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%.
4564	SODIUM BUTYRATE	A, E	The route of administration for medicines that contain sodium butyrate must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 1200 mg sodium butyrate. The following warning statement (or words to the same effect) is required on the medicine label: - (ADULT) 'Adults only'.
4565	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4566	SODIUM CALCIUM EDETATE	E	When for oral use, sodium is a mandatory component of sodium calcium edetate. Sodium calcium edetate must only be included in medicines when: (a) the route of administration is limited to topical for dermal use; or (b) in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of sodium calcium edetate in the medicine must not exceed 0.32%.

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			The total concentration of flavour proprietary excipient formulations containing sodium calcium edetate must not be more than 5% of the total medicine.
4567	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4568	SODIUM CARBONATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4569	SODIUM CARBONATE MONOHYDRATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4570	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%.
4571	SODIUM CARRAGEENAN	E	
4572	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4573	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4574	SODIUM CHLORIDE	A, E, H	
4575	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).
4576	SODIUM CITRATE	A, E	When for use as an active ingredient, only for oral use.
4577	SODIUM CITRATE DIHYDRATE	A, E	When for use as an active ingredient, only for oral use.
4578	SODIUM COCO PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
4579	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4580	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4581	SODIUM CYCLAMATE	E	
4582	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4583	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%.
4584	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4585	SODIUM ERYTHORBATE	E	
4586	SODIUM ETHYL HYDROXYBENZOATE	E	
4587	SODIUM FLUORIDE	A, E, H	Fluoride is a mandatory component of sodium fluoride. The route of administration must be limited to dental. The dosage form must be limited to pastes, powders and/or gels for dental hygiene.

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			<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>
4588	SODIUM FUMARATE	E	
4589	SODIUM HYALURONATE	A, E	<p>When for use as an excipient ingredient, sodium hyaluronate must only be used in medicines with a topical route of administration for dermal application.</p> <p>When for use as an active ingredient:</p> <p>(a) the molecular mass of sodium hyaluronate must be between 600 and 1600 kilodaltons; and</p> <p>(b) sodium hyaluronate must only be used in medicines when the route of administration is limited to:</p> <p>(i) topical for dermal application; or</p> <p>(ii) oral.</p> <p>When for use in a topical medicine for dermal application the concentration of sodium hyaluronate in the medicine must not exceed 2.0%.</p>

			<p>When for use as an active ingredient and the route of administration is oral:</p> <p>(a) the maximum recommended daily dose must not provide more than 200 milligrams sodium hyaluronate;</p> <p>(b) the recommended duration of use of the medicine must be limited to three months; and</p> <p>(c) the following warning statements (or words to the same effect) are required on the medicine label :</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only'; and - (PREGNT) ' Not recommended for use by pregnant and lactating women'.
4590	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4591	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>
4592	SODIUM HYDROXYCITRATE	A	<p>The requirements specified 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 2025; or - released for supply on or after 1 March 2026. <p>When for oral use, the following warning statement is required on the medicine label:</p>

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			<p>‘In very rare cases, sodium hydroxycitrate may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.’</p> <p>Medicines containing sodium hydroxycitrate must not be directed for use in children, or in pregnant or lactating women.</p>
4593	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>
4594	SODIUM HYDROXYMETHYLGLYCINATE	E	<p>Only for use in topical medicines for dermal application.</p>
4595	SODIUM HYPOCHLORITE	E	<p>The pH of the sodium hypochlorite preparation must be less than 11.5.</p>
4596	SODIUM ISOSTEAROYL LACTYLATE	E	<p>Only for use in topical medicines for dermal application.</p>
4597	SODIUM LACTATE	E	
4598	SODIUM LAURETH SULFATE	E	
4599	SODIUM LAUROAMPHOACETATE	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>
4600	SODIUM LAUROYL LACTYLATE	E	<p>Sodium lauroyl lactylate must:</p>

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			(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%.
4601	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%.
4602	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4603	SODIUM LAURYL PHOSPHATE	E	
4604	SODIUM LAURYL SULFATE	E	
4605	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4606	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4607	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%.
4608	SODIUM METABISULFITE	E	
4609	SODIUM METAPHOSPHATE	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must not be more than 0.1%.
4610	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine must be no more than 2%.
4611	SODIUM METHYL HYDROXYBENZOATE	E	
4612	SODIUM MOLYBDATE DIHYDRATE	A	Only for use in oral medicines. Molybdenum is a mandatory component of Sodium molybdate dihydrate. The percentage of molybdenum from sodium molybdate dihydrate should be calculated based on the molecular weight of sodium molybdate dihydrate. The maximum daily dose of molybdenum from Sodium molybdate dihydrate must be no more than 125 micrograms.
4613	SODIUM MONOFLUOROPHOSPHATE	A	Fluoride is a mandatory component of sodium monofluorophosphate. The route of administration must be limited to dental. The dosage form must be limited to pastes, powders and/or gels for dental hygiene. When sodium monofluorophosphate is used as an active ingredient, it is subject to the following conditions: (a) only for use in combination with at least one other active ingredient; and (b) the concentration of fluoride ion in the medicine

			<p>must not be more than 1,500 mg/kg.</p> <p>When the concentration of fluoride ion is more than 1000 mg/kg, the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'
4614	SODIUM MYRISTOYL GLUTAMATE	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 0.0164%.</p>
4615	SODIUM NITRATE	H	<p>Only for use as an active homoeopathic ingredient.</p>
4616	SODIUM NONOXYNOL-4 SULFATE	E	<p>Only for use in topical medicines for dermal application.</p>
4617	SODIUM PANTOTHENATE	A, E, H	
4618	SODIUM PCA	E	<p>Only for use in topical medicines for dermal application.</p>
4619	SODIUM PERBORATE	A, H	<p>Boron is a mandatory component of sodium perborate.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron.</p> <p>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</p>

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not exceed 3500 mg/kg or 3500 mg/L or 0.35%.

When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:

- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or

- (ADULT) 'Adults only' (or words to that effect).

When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:

- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or

- (ADULT) 'Adults only' (or words to that effect).

When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:

- (BORON) 'Contains boron' (or words to that effect).

When the medicine is for topical use for dermal application, the following warning statement is required on the label:

- (BROKEN) 'Use on unbroken skin only' (or words to that effect).

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4620	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.
4621	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4622	SODIUM POLYACRYLATE STARCH	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 1%.
4623	SODIUM POLYMETAPHOSPHATE	E	
4624	SODIUM PROPIONATE	E	
4625	SODIUM PROPYL HYDROXYBENZOATE	E	
4626	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%.
4627	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

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			toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4628	SODIUM SELENATE DECAHYDRATE	A	<p>Selenium is a mandatory component of sodium selenate decahydrate.</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>
4629	SODIUM SELENITE	A, H	<p>Selenium is a mandatory component of Sodium selenite.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'</p>
4630	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</p>

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			of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4631	SODIUM SILICATE	E	
4632	SODIUM STARCH GLYCOLLATE	E	
4633	SODIUM STARCH GLYCOLLATE TYPE A	E	
4634	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4635	SODIUM STEAROXY PG-HYDROXYETHYLCELLULOSE SULFONATE	E	Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
4636	SODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4637	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4638	SODIUM STEARYL PHTHALAMATE	E	Only for use in medicines for dermal application and not to

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			be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4639	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4640	SODIUM SULFATE	A, E, H	When it is not intended to be a laxative, the following warning statement is required on the medicine label: - (LAX4) 'Substance may have a laxative effect'.
4641	SODIUM SULFATE DECAHYDRATE	A, E, H	When it is not intended to be a laxative, the following warning statement is required on the medicine label: - (LAX4) 'Substance may have a laxative effect'.
4642	SODIUM SULFITE	E	
4643	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application.
4644	SODIUM TRIPOLYPHOSPHATE	E	Only for use when the route of administration is topical for dermal application, mucous membrane (buccal mucosa) or dental. Not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4645	SOLANUM DULCAMARA	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum dulcamara. When for internal use, the maximum recommended daily

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			dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4646	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>
4647	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>
4648	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>
4649	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>

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4650	SOLANUM TUBEROSUM	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum tuberosum. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4651	SOLIDAGO GIGANTEA	A, H	
4652	SOLIDAGO GIGANTEA MIS	A, E, H	
4653	SOLIDAGO VIRGAUREA	A, E, H	
4654	SOLUBLE MAIZE STARCH	E	
4655	SOLUBLE POTATO STARCH	E	
4656	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4657	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4658	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4659	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%.
4660	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4661	SOPHORA FLAVESCENS	A, E, H	
4662	SOPHORA TONKINENSIS	A, H	
4663	SORBIC ACID	E	
4664	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4665	SORBITAN MONO-OLEATE	E	
4666	SORBITAN MONOLAURATE	E	
4667	SORBITAN MONOSTEARATE	E	

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4668	SORBITAN OLEATE	E	
4669	SORBITAN OLIVATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
4670	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%.
4671	SORBITAN SESQUISOSTEARATE	E	Only for use in topical medicines for dermal application.
4672	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4673	SORBITAN STEARATE	E	
4674	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4675	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.
4676	SORBITOL SOLUTION (70 PER CENT) (CRYSTALLISING)	A, E	Sorbitol is a mandatory component of sorbitol solution (70 per cent) (crystallising).

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			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.
4677	SORBITOL SOLUTION (70 PER CENT) (NON-CRYSTALLISING)	A, E	Sorbitol is a mandatory component of sorbitol solution (70 per cent) (non-crystallising). When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
4678	SORBUS AUCUPARIA	A, H	
4679	SORGHUM	E	
4680	SORGHUM VULGARE	A, H	
4681	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid. The maximum recommended daily dose of the medicine must not provide more than 300 mg of soy phosphatidylserine.
4682	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder. The maximum recommended daily dose of the medicine must not provide more than 300 mg of soy phosphatidylserine.

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4683	SOY POLYSACCHARIDE	E	
4684	SOY PROTEIN	E	
4685	SOY STEROL	E	
4686	SOYA BEAN	E	
4687	SOYA OIL	A, E, H	
4688	SOYBEAN FLOUR	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4689	SOYBEAN GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4690	SPARGANIUM STOLONIFERUM	A, H	
4691	SPARTIUM JUNCEUM	A, H	
4692	SPATHOLOBUS SUBERECTUS	A, H	
4693	SPEARMINT OIL	A, E, H	Menthol is a mandatory component of spearmint oil. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect).

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(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:

- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;
- (IRRIT) If irritation develops, discontinue use.

(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:

- (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.

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

4694	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> <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>
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- ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;
- iii) the following warning statement is required on the medicine label:
 - (EYE) Avoid contact with eyes (or words to that effect).
- iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:
 - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;
 - (IRRIT) If irritation develops, discontinue use.
- v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:
 - (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.

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

4695	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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4696	SPIGELIA ANTHELMIA	A, H	
4697	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4698	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</p>

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			<p>more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4699	SPINACH	E	
4700	SPINACIA OLERACEA	A, E, H	
4701	SPIRODELA POLYRRHIZA	A, H	
4702	SPIRULINA	E	
4703	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use as an excipient for oral routes of administration.
4704	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use as an excipient for oral routes of administration.
4705	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>
4706	SQUALANE	E	Only for use in topical medicines for dermal application.
4707	SQUALENE	A, E	
4708	SQUID OIL	A	Only for use in oral medicines.

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			<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> <p>- (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.</p>
4709	SQUILL DRY	A, H	
4710	SQUILL INDIAN DRY	A, H	
4711	SQUILL INDIAN POWDER	A, H	
4712	SQUILL POWDER	A, H	
4713	ST JOHN'S WORT DRY EXTRACT QUANTIFIED	A	<p>When used for oral ingestion, the medicine requires the following warning statement on the medicine label:</p> <p>- (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'</p>
4714	ST JOHN'S WORT HERB DRY	A, H	<p>When used for oral ingestion, the medicine requires the following warning statement on the medicine label:</p> <p>- (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'</p>
4715	ST JOHN'S WORT HERB POWDER	A, H	<p>When used for oral ingestion, the medicine requires the following warning statement on the medicine label:</p> <p>- (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'</p>

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4716	STACHYS OFFICINALIS	A, E, H	
4717	STACHYS PALUSTRIS	A, H	
4718	STACHYURUS HIMALAICUS	A, H	
4719	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%.
4720	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4721	STAR ANISE OIL	A, E	When the total concentration of star anise oil in the medicine is more than 50%: (a) the nominal capacity of the container must not be more than 50 mL; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4722	STARCH	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4723	STARCH SODIUM OCTENYL SUCCINATE	E	
4724	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.

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4725	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4726	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4727	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4728	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4729	STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 2%. When the medicine is intended to be used on the eye, the medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4730	STEARETH-10	E	Only for use in topical medicines for dermal application.
4731	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%.
4732	STEARETH-2	E	Only for use in topical medicines for dermal application.

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4733	STEARETH-20	E	Only for use in topical medicines for dermal application.
4734	STEARETH-21	E	Only for use in topical medicines for dermal application.
4735	STEARETH-5	E	Only for use in topical medicines for dermal application.
4736	STEARIC ACID	E	
4737	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%.
4738	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%.
4739	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4740	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4741	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4742	STEARYL ALCOHOL	E	

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4743	STEARYL BEHENATE	E	<p>Only for use as an excipient ingredient 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 3.5% in the final formulation.</p>
4744	STEARYL 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 4.5%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (EYE2) 'May be irritant to the eyes' (or words to that effect) - (EYE) 'Avoid contact with eyes' (or words to that effect).
4745	STEARYL GLYCYRRHETINATE	E	<p>Only for use in topical medicines for dermal application.</p>
4746	STEARYL HEPTANOATE	E	<p>Only for use in topical medicines for dermal application.</p>
4747	STEARYL MYRISTATE	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>
4748	STEARYL STEARATE	E	<p>Only for use in topical medicines for dermal application.</p>

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4749	STELLARIA CHAMAEJASME	A, H	
4750	STELLARIA DICHOTOMA	A, H	
4751	STELLARIA MEDIA	A, E, H	
4752	STEMONA JAPONICA	A, H	
4753	STEMONA SESSILIFOLIA	A, H	
4754	STENOTAPHRUM SECUNDATUM	A, H	
4755	STEPHANIA TETRANDA	A, H	
4756	STERCULIA	A, H	
4757	STERCULIA TRAGACANTHA	A, H	
4758	STERCULIA URENS	A, H	
4759	STEVIA REBAUDIANA	A, E, H	
4760	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4761	STILLINGIA SYLVATICA	A, H	
4762	STORAX PREPARED	A, E, H	
4763	STRAWBERRY	E	
4764	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%.
4765	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'.
4766	STREPTOCOCCUS THERMOPHILUS	A	

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4767	STROBILANTHES CUSIA	A, H	
4768	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%.
4769	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4770	STROPHANTHUS GRATIS	H	Only for use as an active homoeopathic ingredient.
4771	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4772	STRYCHNOS IGNATII	H	Only for use as an active homoeopathic ingredient. Strychnine (of Strychnos spp.) is a mandatory component of Strychnos ignatii. The concentration of Strychnine (of Strychnos spp.) must not be more than 1 milligram/Kg or 1 milligram/L or 0.0001%.
4773	STRYCHNOS NUX-VOMICA	A, H	Strychnine (of Strychnos spp.) is a mandatory component of Strychnos nux-vomica. The concentration of Strychnine (of Strychnos spp.) must not be more than 1 milligram/Kg or 1 milligram/L or 0.0001%.
4774	STYPHNOLOBIUM JAPONICUM	A, E, H	
4775	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%.
4776	STYRAX BENZOIN	A, E, H	
4777	STYRAX OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4778	STYRAX PARALLELONEURUM	A, H	
4779	STYRAX TONKINENSIS	A, H	
4780	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%.
4781	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4782	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%.

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4783	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4784	SUCCINIC ACID	E	
4785	SUCRALOSE	E	
4786	SUCROSE	E	
4787	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%.
4788	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%.
4789	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%.
4790	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4791	SUCROSE LAURATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate.
4792	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.

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4793	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4794	SUCROSE POLYCOTTONSEEDATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with the eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4795	SUCROSE STEARATE	E	For use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When for topical use, the concentration in the medicine must be no more than 0.25%. For oral use as a manufacturing aid only. When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit.
4796	SUCROSE TRISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
4797	SUDAN III	E	Permitted for use only as a colour for topical use.

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4798	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 (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 (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>
4799	SUGARCANE	E, H	<p>When for oral or sublingual use, sucrose is a mandatory component of sugarcane.</p>
4800	SULFATED CASTOR OIL	E	<p>Only for use in topical medicines for dermal application.</p>

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4801	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%.
4802	SULFUR DIOXIDE	E	
4803	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4804	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%.
4805	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%.
4806	SULISOBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

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4807	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).
4808	SUNFLOWER OIL	A, E, H	
4809	SUNFLOWER SEED	E, H	
4810	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4811	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
4812	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4813	SWEDE	E	
4814	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>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4815	SWEET POTATO	E	
4816	SWERTIA CHIRATA	A, H	
4817	SWIETENIA MAHOGANI	A, H	
4818	SYAGRUS ROMANZOFFIANA	A, E, H	
4819	SYMPHYOTRICHUM NOVI-BELGII	A, H	
4820	SYMPHYTUM OFFICINALE	H	When used orally as an active homoeopathic ingredient, the concentration must be a dilution of 12X or more. When used in topical medicines for dermal application, the concentration in the preparation must be no more than 10mg/kg or 10mg/L or 0.001%.
4821	SYMPLOCARPUS FOETIDUS	A, H	
4822	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4823	SYNTHETIC TERPENE RESIN	E	Only for use in topical, oral or oral application medicines. When the route of administration is oral, the dosage form must be chewing gum.
4824	SYNTHETIC WAX	E	
4825	SYRINGA RETICULATA	A, H	
4826	SYRINGA VULGARIS	A, H	
4827	SYZYGIUM AROMATICUM	A, E, H	When the plant preparation is oil or distillate and the concentration of this oil or distillate in the product is greater than 25%, the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning

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			statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the plant preparation is oil or distillate, the concentration of this oil or distillate in the medicine is greater than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, a child resistant closure and restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate, the concentration of oil or distillate in the product is greater than 25% and the nominal capacity of the container is less than 15 millilitres, a restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate and the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of the oil or distillate and the concentration of oil or distillate in the product must not be greater than 25%.
4828	SYZYGIUM CUMINI	A, H	
4829	SYZYGIUM JAMBOS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 0.0693%.
4830	TABEBUIA SERRATIFOLIA	A, E, H	
4831	TADEHAGI TRIQUETRUM	A, H	

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4832	TAGETES ERECTA	A, E, H	When used as an excipient ingredient, only for use in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
4833	TAGETES MINUTA	A, E, H	
4834	TAGETES OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4835	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4836	TALLOW	E	Only for use in topical medicines for dermal application.
4837	TALLOW GLYCERIDES	E	
4838	TAMARINDUS INDICA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4839	TAMARIX APHYLLA	A, H	
4840	TAMARIX CHINENSIS	A, H	
4841	TAMARIX GALLICA	A, H	

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4842	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.
4843	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4844	TANACETUM COCCINEUM SUBSP. COCCINEUM	A, H	
4845	TANACETUM PARTHENIUM	A, E, H	
4846	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%.
4847	TANGERINE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4848	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.
4849	TANNIC ACID	E	
4850	TAPIOCA STARCH	E	
4851	TARAXACUM MONGOLICUM	A, E, H	
4852	TARAXACUM OFFICINALE	A, E, H	
4853	TARO	E	

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4854	TARRAGON OIL	A, E, H	
4855	TARTARIC ACID	E	
4856	TARTRAZINE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4857	TARTRAZINE ALUMINIUM LAKE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4858	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%.
4859	TAURINE	A, E	
4860	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4861	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'.
4862	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.

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4863	TERMINALIA CATAPPA	A, H	
4864	TERMINALIA CHEBULA	A, H	
4865	TERMINALIA FERDINANDIANA	A, E, H	<p>When used as an active ingredient:</p> <p>(a) the plant part must be from fruit flesh or seed only; and</p> <p>(b) the plant preparation must be limited to fresh, dry, powder, and extraction preparations with water as the only solvent.</p> <p>When used as an excipient ingredient:</p> <p>(a) the route of administration for medicines that contain Terminalia ferdinandiana must be limited to topical for dermal use;</p> <p>(b) medicines that contain Terminalia ferdinandiana are not to be intended for use on damaged skin or in the eye; and</p> <p>(c) the concentration of Terminalia ferdinandiana in the medicine must not be more than 0.3%.</p>
4866	TERMINALIA SERICEA	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>Only for use when the plant part is root bark.</p> <p>Only methanol/water (90:10; V/V) extract of Terminalia sericea bark of the root is approved.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
4867	TERPENE RESIN	E	<p>Terpene resin must only be included in medicines when in combination with other</p>

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			permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application.
4868	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%.
4869	TERPINEOL	E	
4870	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%.
4871	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%.
4872	TERPINYL ACETATE	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>
4873	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>
4874	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>
4875	TERT-BUTYL ALCOHOL	E	<p>Only for use in topical medicines for dermal application.</p>
4876	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>
4877	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>

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4878	TERT-BUTYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4879	TETRACLINIS ARTICULATA	A, E, H	
4880	TETRADECYL AMINOBUTYROYLVALYLAMIN OBUTYRIC UREA TRIFLUOROACETATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
4881	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.
4882	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%.
4883	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%.

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4884	TETRAHYDRO PARA-METHYLQUINOLINE	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>
4885	TETRAHYDRO-6-(3-PENTENYL)-2H-PYRAN-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>
4886	TETRAHYDRODIFERULOYLME THANE	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>
4887	TETRAHYDROFURFURYL 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>
4888	TETRAHYDROGERANYL 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>

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4889	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%.
4890	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%.
4891	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%.
4892	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4893	TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4894	TETRAPANAX PAPYRIFER	A, H	
4895	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.

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4896	TETRASODIUM PYROPHOSPHATE	E	
4897	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of <i>Teucrium chamaedrys</i> .
4898	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of <i>Teucrium marum</i> .
4899	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of <i>Teucrium scorodonia</i> .
4900	THAPSIA GARGANICA	A, H	
4901	THAUMATIN	E	
4902	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>

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			- (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'.
4903	THEASPIRANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4904	THEMEDA TRIANDRA	A, H	
4905	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma cacao. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. When the maximum recommended daily dose of the medicine provides greater than

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			<p>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).
4906	THEOBROMA OIL	A, E, H	
4907	THIAMINE	A, E	
4908	THIAMINE HYDROCHLORIDE	A, E	
4909	THIAMINE NITRATE	A, E	
4910	THIOCINEOLE	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</p>

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			medicine must be no more than 1%.
4911	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%.
4912	THLASPI ARVENSE	A, E, H	
4913	THREONINE	A, E	
4914	THUJA OCCIDENTALIS	A, H	
4915	THUJA PLICATA	A, E, H	
4916	THYME HERB DRY	A, E, H	
4917	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).
4918	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.
4919	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.
4920	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).
4921	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4922	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).
4923	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).

4924	THYMUS VULGARIS	A, E, H	<p>When the plant preparation is oil or distillate, and the concentration of 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>
4925	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>
4926	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>

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			(c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4927	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4928	TILACTASE	A	Must be derived from <i>Aspergillus oryzae</i> and comply with the relevant USP monograph.
4929	TILIA CORDATA	A, E, H	
4930	TILIA PLATYPHYLLOS	A, E, H	
4931	TILIA TOMENTOSA	A, H	
4932	TILIA X VULGARIS	A, E, H	
4933	TILIANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4934	TIN	H	Only for use as an active homoeopathic ingredient.
4935	TINOSPORA CORDIFOLIA	A, H	
4936	TINOSPORA SINENSIS	A, H	
4937	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.

			<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).
4938	TOCOCYSTEAMIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.01%.</p>
4939	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>
4940	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>

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4941	TOCOPHERYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. The concentration in the medicine must be no more than 0.05%
4942	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4943	TOCOPHERYL NICOTINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must not exceed 0.3%.
4944	TOLU BALSAM	A, E, H	
4945	TOLUENE	E	The residual solvent limit for toluene is 8.9 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.089%.
4946	TOLYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4947	TOLYLALDEHYDE GLYCERYLACETAL	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%.
4948	TOMATO	E	
4949	TONKA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4950	TONKA BEAN EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4951	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%.
4952	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4953	TOXICODENDRON PUBESCENS	H	Only for use as an active homoeopathic ingredient. The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron pubescens.

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4954	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4955	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4956	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4957	TRACHYSPERMUM AMMI	A, E	<p>Only for use in oral medicines when the plant part is fruit or seed.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect). <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>
4958	TRAGACANTH	A, E	
4959	TRAMETES VERSICOLOR	A, H	
4960	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4961	TRANS,TRANS-2,4-DECADIEN-1-AL	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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4962	TRANS,TRANS-2,4- HEXADIENAL	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 the medicine must be no more than 1%.</p> <p>The maximum daily dose must provide no more than 13.5 mg of Trans,Trans-2,4-Hexadienal.</p>
4963	TRANS-1-(2,4,4-TRIMETHYL-2-CYCLOHEXEN-1-YL)-2-BUTEN-1-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>
4964	TRANS-2-DECENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4965	TRANS-2-DODECENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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4966	TRANS-2-HEPTEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4967	TRANS-2-HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4968	TRANS-2-HEXENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4969	TRANS-2-HEXENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4970	TRANS-2-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			medicine must be no more than 5%.
4971	TRANS-2-HEXENYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4972	TRANS-2-HYDROXYCINNAMIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4973	TRANS-2-OCTENAL	E	trans-2-Octenal must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing trans-2-octenal must not be more than 1% of the total medicine.
4974	TRANS-2-UNDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4975	TRANS-3-HEXENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			medicine must be no more than 5%.
4976	TRANS-4-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4977	TRANS-8-(1-METHYLETHYL)-1-OXASPIRO(4.5)DECAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4978	TRANS-ETHYL 2-OCTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4979	TRANS-METHYL-2-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4980	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of treacle.
4981	TREEMOSS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.

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			<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> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
4982	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>
4983	TREHALOSE DIHYDRATE	E	<p>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.</p>
4984	TREMELLA FUCIFORMIS	A, H	
4985	TRIACETIN	E	
4986	TRIACONTANYL PVP	E	<p>Only for use in topical medicines for dermal application.</p>
4987	TRIADICA SEBIFERA	A, H	

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4988	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 pH of the medicine must be no more than 11.5.</p>
4989	TRIBASIC SODIUM PHOSPHATE	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>
4990	TRIBEHENIN	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>
4991	TRIBEHENIN PEG-20 ESTERS	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>
4992	TRIBULUS TERRESTRIS	A, E, H	
4993	TRIBUTYL ACETYLCITRATE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4994	TRICALCIUM PHOSPHATE	E	
4995	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%.
4996	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%.
4997	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4998	TRICHLOROMETHYLPHENYL ARBINYL 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%.
4999	TRICHODERMA VIRIDE	A, E, H	
5000	TRICHOSANTHES KIRILOVII	A, E, H	
5001	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
5002	TRICYCLODECENYL PROPIONATE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5003	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%.
5004	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
5005	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%.
5006	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%.
5007	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
5008	TRIDECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal

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			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%.
5009	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%.
5010	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
5011	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
5012	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%.
5013	TRIETHYL CITRATE	E	
5014	TRIETHYLENE GLYCOL	E	
5015	TRIFOLIUM PRATENSE	A, E, H	
5016	TRIFOLIUM REPENS	A, H	
5017	TRIGONELLA FOENUM- GRAECUM	A, E, H	
5018	TRIHYDROXPALMITAMIDOH YDROXYPROPYL MYRISTYL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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			The concentration in the medicine must be no more than 0.02%.
5019	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
5020	TRISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
5021	TRISODECYL 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%.
5022	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%.
5023	TRISOSTEARIN	E	Only for use in topical medicines for dermal application.
5024	TRILAURIN	E	Only for use in topical medicines for dermal application.
5025	TRILISA ODORATISSIMA	A, H	
5026	TRILLIUM ERECTUM	A, H	
5027	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.

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			The concentration in the medicine must be no more than 0.25%.
5028	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%.
5029	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%.
5030	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%.
5031	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%.
5032	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%.

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5033	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5034	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%.
5035	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5036	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%.
5037	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%.
5038	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%.
5039	TRIOLEIN	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
5040	TRIOSTEUM PERFOLIATUM	A, H	
5041	TRIOXAUNDECANEDIOIC ACID	E	
5042	TRIPLEPTIDE-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%.
5043	TRIS-BIPHENYL TRIAZINE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used topically, the dosage form must not be spray. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
5044	TRISILOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 40%.

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5045	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
5046	TRISODIUM ETHYLENEDIAMINE DISUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
5047	TRISODIUM NTA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
5048	TRISTEARIN	E	
5049	TRITICUM AESTIVUM	A, E, H	Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal.
5050	TRITICUM DURUM	A, E, H	Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal.
5051	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%.

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5052	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5053	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
5054	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).
5055	TROLLIUS CHINENSIS	A, H	
5056	TROMETAMOL	E	
5057	TROMETAMOL HYDROCHLORIDE	E	
5058	TROPAEOLUM MAJUS	A, E, H	
5059	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5060	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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5061	TSUGA CANADENSIS	A, H	
5062	TULIPA EDULIS	A, H	Colchicine is a mandatory component of Tulipa edulis. The concentration of colchicine in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
5063	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5064	TURNERA DIFFUSA	A, E, H	Beta-arbutin is a mandatory component of Turnera diffusa. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5065	TURNIP	E	
5066	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%.

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5067	TYPHA ANGUSTIFOLIA	A, H
5068	TYPHA LATIFOLIA	A, H
5069	TYPHONIUM GIGANTEUM	A, H
5070	TYROSINE	A, E
