

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
3636	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>
3637	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>
3638	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).
3639	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%.
3640	PAEONIA LACTIFLORA	A, E, H	
3641	PAEONIA OBOVATA	A, H	
3642	PAEONIA SUFFRUTICOSA	A, E, H	
3643	PAEONIA VEITCHII	A, H	
3644	PALIURUS SPINA-CHRISTI	A, H	
3645	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3646	PALM FRUIT OIL	A, E, H	
3647	PALM GLYCERIDES	E	
3648	PALM KERNEL OIL	A, E, H	
3649	PALM TOCOTRIENOLS COMPLEX	A, H	
3650	PALMARIA PALMATA	A, H	
3651	PALMAROSA OIL	A, E, H	
3652	PALMIDROL	A	Only permitted for use in medicines limited to oral routes of administration. The maximum recommended daily dose of the medicine must not provide more than 600 mg of palmidrol. The following warning statements (or words to the same effect) are required on the medicine label: - (ANALG) 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.'

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			- (ADULT) 'Adults only.'
			- (21DAYS) 'Not to be used for more than 21 consecutive days.'
3653	PALMITIC ACID	E	
3654	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3655	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%.
3656	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%
3657	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%.
3658	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%.
3659	PALMITOYL TETRAPEPTIDE-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.001%.

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3660	PANAX GINSENG	A, E, H	
3661	PANAX JAPONICUS	A, H	
3662	PANAX NOTOGINSENG	A, H	
3663	PANAX PSEUDOGINSENG	A, H	
3664	PANAX QUINQUEFOLIUS	A, H	
3665	PANICUM MILIACEUM	A, H	
3666	PANTETHINE	E	Only for use in topical medicines for dermal application.
3667	PANTHENOL	A, E	
3668	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3669	PANTOLACTONE	E	
3670	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3671	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%.
3672	PAPAIN	A, E	
3673	PAPER	E	Only for use in topical medicines for dermal application.
3674	PAPRIKA OLEORESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3675	PARA-CRESOL	E	Permitted for use only in combination with other permitted

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			<p>ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3676	PARA-CRESYL 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>
3677	PARA-CRESYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3678	PARA-CRESYL PHENYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3679	PARA-CYMENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a</p>

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3680	<p>PARA-ETHOXYBENZALDEHYDE</p>	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>
3681	<p>PARA-ETHYL CRESOXYACETATE</p>	E	<p>Para-ethyl cresoxyacetate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing para-ethyl cresoxyacetate must not be more than 1% of the total medicine.</p>
3682	<p>PARA-ETHYLPHENOL</p>	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The maximum recommended daily dose must contain no more than 0.12 mg of para-ethylphenol.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
3683	<p>PARA-HYDROXY BENZALACETONE</p>	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%.
3684	PARA-HYDROXYBENZOIC ACID	E	
3685	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%.
3686	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%.
3687	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%.
3688	PARA-METHYL DIMETHYLBENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3689	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>
3690	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>
3691	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>
3692	PARA-TOLUALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a</p>

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			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3693	PARA-TOLYL ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3694	PARAMERIA LAEVIGATA	A, H	
3695	PARIETARIA JUDAICA	A, H	
3696	PARIS POLYPHYLLA	A, H	
3697	PARIS QUADRIFOLIA	A, H	
3698	PARSLEY HERB DRY	A, E, H	
3699	PARSLEY HERB OIL	A, E, H	
3700	PARSLEY HERB POWDER	A, E, H	
3701	PARSLEY SEED OIL	A, E, H	
3702	PARTHENOCISSUS TRICUSPIDATA	A, H	
3703	PARTIALLY DEHYDRATED LIQUID SORBITOL	E	Sorbitol is a mandatory component of partially dehydrated liquid sorbitol. Permitted for use only as part of the capsule in medicines where the dosage form is a soft capsule.
3704	PARTIALLY HYDROGENATED SOYA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.

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3705	PARTIALLY REFINED PORPHYRA YEZOENSIS CYTOPLASM EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.00002%.
3706	PASPALUM NOTATUM	A, H	
3707	PASSIFLORA CAERULEA	A, H	
3708	PASSIFLORA EDULIS	E	
3709	PASSIFLORA HERB DRY	A, H	
3710	PASSIFLORA INCARNATA	A, E, H	
3711	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%.
3712	PATENT BLUE V	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3713	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3714	PATRINIA SCABIOSIFOLIA	A, H	
3715	PATRINIA VILLOSA	A, H	
3716	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

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			oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
3717	PAULLINIA PINNATA	A, H	
3718	PAWPAW	E	
3719	PEA	E	
3720	PEA STARCH	E	
3721	PEACH	E	
3722	PEAR	E	
3723	PECAN	E	
3724	PECTIN	A, E	
3725	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%.
3726	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3727	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3728	PEG-12 DILAURATE	E	
3729	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.

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			The concentration in the medicine must be no more than 2%.
3730	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3731	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3732	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3733	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3734	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%.
3735	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3736	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3737	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3738	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3739	PEG-25 PABA	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%.

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			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).
3740	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3741	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3742	PEG-35 CASTOR OIL	E	
3743	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3744	PEG-4 LAURATE	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of PEG-4 laurate. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3745	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3746	PEG-40 CASTOR OIL	E	
3747	PEG-40 HYDROGENATED CASTOR OIL	E	

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3748	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>
3749	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3750	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3751	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3752	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3753	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>
3754	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3755	PEG-60 ALMOND GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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			<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>
3756	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>
3757	PEG-60 HYDROGENATED CASTOR OIL	E	<p>Only for use in topical medicines for dermal application.</p>
3758	PEG-7 COCAMIDE	E	<p>Only for use in topical medicines for dermal application.</p>
3759	PEG-7 GLYCERYL COCOATE	E	<p>Only for use in topical medicines for dermal application.</p>
3760	PEG-7 HYDROGENATED CASTOR OIL	E	<p>Only for use in topical medicines for dermal application.</p>
3761	PEG-75 LANOLIN	E	<p>Only for use in topical medicines for dermal application.</p>
3762	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> <p>The concentration in the medicine must be no more than 1.5%.</p>
3763	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>

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3764	PEG-8 DILAURATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
3765	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3766	PEG-8 LAURATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. The levels of possible impurities such as ethylene oxide (and related material) must be kept below the level of detection.
3767	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3768	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3769	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%.
3770	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%.

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3771	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%.
3772	PELARGONIUM GRAVEOLENS	A, E, H	
3773	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%.
3774	PELTIGERA CANINA	A, H	
3775	PENICILLIUM EXPANSUM	A, H	
3776	PENNYROYAL OIL	E	D-Pulegone/Pulegone is a mandatory component of Pennyroyal Oil. The concentration of D Pulegone/ Pulegone in the medicine must be no more than 4%. Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in the medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. When the medicine is for a use other than topical, the maximum recommended daily dose must be no more than 50 mg of Pennyroyal Oil.

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3777	PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.018%
3778	PENTAERYTHRITYL TETRAISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 61%.
3779	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3780	PENTAMETHYLHEPTENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3781	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%.
3782	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.

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			The concentration in the medicine must be no more than 0.1%.
3783	PENTYLENE GLYCOL	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>
3784	PEPPER BLACK	E, H	
3785	PEPPER OIL TERPENELESS	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>
3786	PEPPERMINT AMERICAN EXT.	E	<p>Menthol is a mandatory component of peppermint american ext.</p> <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>
3787	PEPPERMINT LEAF DRY	A, E, H	<p>Menthol is a mandatory component of peppermint leaf dry.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small</p>

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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.

3788	PEPPERMINT LEAF POWDER	A, E, H	<p>Menthol is a mandatory component of peppermint leaf powder.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small</p>
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			<p>area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>- (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3789	PEPPERMINT OIL	A, E, H	<p>Menthol is a mandatory component of peppermint oil.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p>

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- (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 OIL TERPENELESS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more 1%.</p> <p>Menthol is a mandatory component of peppermint oil terpeneless.</p> <p>When the medicine is for topical use for dermal application:</p> <p>i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>iii) the following warning statement is required on the medicine label:</p>
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			<p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3791	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>

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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.

3792	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3793	PERHYDRO-3,6-DIMETHYLBENZO [B] FURAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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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>
3794	PERILLA FRUTESCENS	A, E, H	
3795	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>
3796	PERLITE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p>
3797	PERMETHRIN	E	<p>The total concentration of permethrin in the medicine must not be more than 2%.</p>
3798	PERSEA AMERICANA	A, E, H	
3799	PERSIC OIL	A, E, H	<p>Amygdalin and Hydrocyanic acid are mandatory components of Persic oil.</p> <p>The concentration of amygdalin in the medicine must be no more than 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
3800	PERSICARIA CHINENSIS	A, H	

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3801	PERSICARIA TINCTORIA	A, H	
3802	PERU BALSAM	A, E, H	
3803	PERU BALSAM OIL	A, E, H	
3804	PETITGRAIN MANDARIN OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour</p> <p>The final concentration of the oil in the flavour does not exceed 30%</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%</p>
3805	PETITGRAIN OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3806	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>

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3807	PETITGRAIN OIL PARAGUAY	A, E, H	When used internally, oxedrine is a mandatory component of petitgrain oil paraguay. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3808	PETITGRAIN OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3809	PETROSELINUM CRISPUM	A, E, H	
3810	PEUCEDANUM PRAERUPTORUM	A, E, H	
3811	PEUMUS BOLDUS	A, H	Volatile oil components (of Peumus boldus) is a mandatory component. The maximum recommended daily dose must be no more than 100 mg of volatile oil components (of Peumus boldus).
3812	PHALARIS ARUNDINACEA	A, H	
3813	PHALARIS CANARIENSIS	A, H	
3814	PHASEOLUS COCCINEUS	A, H	
3815	PHASEOLUS VULGARIS	A, H	
3816	PELLINUS ROBINIAE	A, E, H	
3817	PHELLODENDRON AMURENSE	A, E, H	
3818	PHELLODENDRON CHINENSE	A, H	
3819	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.

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3820	PHENETHYL 2-METHYLBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3821	PHENETHYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3822	PHENETHYL ALCOHOL	E	<p>Permitted for use only:</p> <p>a) in topical medicines for dermal application; and</p> <p>b) for internal use in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation concentration in a medicine must be no more than 5%.</p>
3823	PHENETHYL BENZOATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 6%.</p>

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3824	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%
3825	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%.
3826	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%.
3827	PHENETHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3828	PHENETHYL PHENYLACETATE	E	Permitted for use only in combination with other permitted

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			<p>ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3829	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>
3830	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>
3831	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>
3832	PHENOXYETHANOL	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration of phenoxyethanol in the preparation must not exceed 15%.</p>

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3833	PHENOXYETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3834	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
3835	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3836	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3837	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%.
3838	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3839	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%.
3840	PHENYLACETIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3841	PHENYLALANINE	A, E	When the maximum recommended daily dose of the medicine provides more than 500 mg phenylalanine, the following warning statement is required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.
3842	PHENYLBENZIMIDAZOLE SULFONIC ACID	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 4%. When used in primary sunscreen products, the following warning

			statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3843	PHENYLETHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3844	PHENYLETHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3845	PHENYLETHYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3846	PHENYLETHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
3847	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>
3848	PHENYLETHYL METHYLETHYL CARBINOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3849	PHENYLETHYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3850	PHENYLETHYL TIGLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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3851	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%.
3852	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%.
3853	PHLEUM PRATENSE	A, H	Only permitted in preparations other than phleum pratense pollen extract.
3854	PHLOXINE B	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3855	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3856	PHOENIX DACTYLIFERA	A, E, H	
3857	PHOSPHATIDYL CHOLINE	E	
3858	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%.
3859	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3860	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient.

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			The total concentration of phosphorus in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.
3861	PHOTINIA SERRULATA	A, H	
3862	PHRAGMITES AUSTRALIS	A, H	
3863	PHYLLANTHUS AMARUS	A, H	
3864	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
3865	PHYLLOSTACHYS NIGRA	A, E, H	
3866	PHYSALIS ALKEKENGII	A, H	
3867	PHYSALIS PUBESCENS	A, H	
3868	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
3869	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%.
3870	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3871	PHYTOMENADIONE	A, E	
3872	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%.

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3873	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%.
3874	PICEA ABIES	A, H	
3875	PICEA MARIANA	A, H	
3876	PICRAMISMA EXCELSA	A, E, H	
3877	PICRORRHIZA KURROA	A, E, H	
3878	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%.
3879	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%.
3880	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%.
3881	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3882	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3883	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.

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3884	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3885	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.
3886	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3887	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3888	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.
3889	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%.
3890	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%.
3891	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%.
3892	PIMENTA FRUIT OIL	A, E, H	
3893	PIMENTA LEAF OIL	A, E, H	

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3894	PIMENTA OFFICINALIS	A, E, H	
3895	PIMENTA RACEMOSA	A, E, H	<p>When the plant preparation for <i>Pimenta racemosa</i> is an oil and the concentration of this oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the plant preparation for <i>Pimenta racemosa</i> is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL, a restricted flow insert must be fitted on the container.</p> <p>When the plant preparation for <i>Pimenta racemosa</i> is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'.
3896	PIMPINELLA ANISUM	A, E, H	<p>When the plant preparation for <i>Pimpinella anisum</i> is an oil or distillate and the concentration of this oil or 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

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			c) the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3897	PIMPINELLA SAXIFRAGA	A, E, H	
3898	PINE NEEDLE OIL SCOTCH	A, E, H	
3899	PINE NEEDLE OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3900	PINE OIL AROMATIC	A, E, H	
3901	PINE OIL PUMILIO	A, E, H	
3902	PINEAPPLE	E	
3903	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%.
3904	PINELLIA TERNATA	A, H	
3905	PINUS CONTORTA	A, E, H	
3906	PINUS ELLIOTTII	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3907	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%.
3908	PINUS MONTICOLA	A, E, H	
3909	PINUS MUGO	A, E, H	
3910	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%.
3911	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%.
3912	PINUS PONDEROSA	A, E, H	
3913	PINUS RADIATA	A, E, H	
3914	PINUS STROBUS	A, E, H	
3915	PINUS SYLVESTRIS	A, E, H	
3916	PINUS TABULIFORMIS	A, E, H	
3917	PINUS YUNNANENSIS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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3918	PIPENZOLATE BROMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3919	PIPER CHABA	A, E, H	
3920	PIPER CUBEBA	A, E, H	
3921	PIPER KADSURA	A, E, H	
3922	PIPER LONGUM	A, E, H	
3923	PIPER METHYSTICUM	A, H	Kavalactones (of Piper methysticum) is a mandatory component of Piper methysticum. Only for oral use when the dosage form is 'tablet' or 'capsule'; or when the container type is 'tea bag'. When used in oral medicines, the maximum daily dose of kavalactones (of Piper methysticum) must be no more than 250 mg. If the dosage form is tablet or capsule then the quantity of kavalactones (of Piper methysticum) must be no more than 125 mg per tablet or capsule. Oral medicines containing more than 25 mg of kavalactones (of Piper methysticum) per dose require the following warning statement on the medicine label: - (PIPER) 'Not for prolonged use. If symptoms persist - seek advice from a healthcare practitioner. Not recommended for pregnant or lactating women (or words to that effect). May harm the liver'. The plant part must be root or rhizome. When for oral use, the medicine may only contain dried whole or

			<p>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>
3924	PIPER NIGRUM	A, E, H	
3925	PIPER SARMENTOSUM	A, E, H	
3926	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 medicine must not be more than 0.15%.</p>
3927	PIPERITONE	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>
3928	PIPERONAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a</p>

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3929	PIPERONYL ACETONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3930	PIPERONYL BUTOXIDE	E	<p>Only for use in topical medicines for dermal application.</p>
3931	PIROCTONE OLAMINE	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% in wash-on/wash-off medicines and 0.5% in leave-on medicines.</p>
3932	PISCIDIA PISCIPULA	A, E, H	
3933	PISTACIA LENTISCUS	A, E, H	
3934	PISUM SATIVUM	A, E, H	
3935	PLACENTA	H	<p>Only for use as an active homoeopathic ingredient.</p>
3936	PLANTAGO AFRA	A, E, H	<p>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:</p>

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			- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3937	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).
3938	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).
3939	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).
3940	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).
3941	PLANTAGO OVATA	A, H	When a dose for children is stated and the plant part is flower, seed

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			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 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).
3943	PLATANUS OCCIDENTALIS	A, E, H	
3944	PLATANUS RACEMOSA	A, H	
3945	PLATANUS × HISPANICA	A, H	
3946	PLATYCODON GRANDIFLORUS	A, E, H	
3947	PLECTRANTHUS BARBATUS	A, E, H	
3948	PLICATONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3949	PLUM	E	
3950	PLUMBAGO EUROPAEA	A, H	
3951	PLUMERIA ALBA	A, E, H	
3952	PLUMERIA RUBRA	A, E, H	
3953	POA NEMORALIS	A, H	
3954	POA PRATENSIS	A, H	
3955	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

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			must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3956	POGOSTEMON CABLIN	A, E, H	
3957	POLACRILIN	E	
3958	POLACRILIN POTASSIUM	E	
3959	POLAPREZINC	A	<p>Only for use in oral medicines.</p> <p>Zinc is a mandatory component of Polaprezinc.</p> <p>The maximum recommended daily dose must be no more than 34 milligrams of zinc sourced from polaprezinc.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:</p> <p>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect).</p>
3960	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>

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- (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect).

When for internal use and the dosage form is a powdered preparation, the following warning statement is required on the medicine label:

- (DNTPOW) 'Do not take powder alone. Mix with food or fluid'.

When used as an excipient, only for use in topical medicines for dermal application.

3961	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> <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.';</p> <p>and</p> <p>(c) if the medicine is a powdered dosage form, the following warning statement is also required on the medicine label:</p> <p>- (DNTPOW) 'Do not take powder alone. Mix with food or fluid.'</p> <p>When used as an excipient, Poliglusam derived from <i>Aspergillus niger</i> is only permitted for use in topical medicines for dermal application.</p>
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3962	POLLACK-LIVER OIL	A, E	<p>Colecalciferol and Vitamin A are mandatory components of Pollack-liver oil.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use. - (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use. - (VITA3) ‘The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’ <p>When for internal use, the maximum recommended daily</p>
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			dose must be no more than 25 micrograms of Vitamin D.
3963	POLLEN	E	The medicine requires the following warning statement on the medicine label: - (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect).
3964	POLOXAMER	E	Only for use in topical medicines for dermal application.
3965	POLOXAMINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3966	POLY C10-30 ALKYL ACRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3967	POLYACRYLAMIDE	E	Only for use in topical medicines for dermal application. Acrylamide is a mandatory component of Polyacrylamide. The concentration of Acrylamide in the medicine must be no more than 0.01%.
3968	POLYACRYLATE CROSSPOLYMER-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.

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3969	POLYACRYLATE-1 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.4%.
3970	POLYACRYLIC ACID	E	
3971	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3972	POLYAMINOPROPYL BIGUANIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.
3973	POLYBUTADIENE	E	Only for use as part of an adhesive in topical medicines for dermal application.
3974	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3975	POLYBUTYLENE GLYCOL/PPG- 9/1 COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3976	POLYCAPROLACTONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.

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3977	POLYDECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3978	POLYDEXTROSE	E	
3979	POLYDIETHYLSILOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
3980	POLYDIMETHYL SILOXANE	E	Permitted for use only in combination with other permitted ingredients as a printing ink. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
3981	POLYESTER-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3982	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%.
3983	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.

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			The concentration in the medicine must be no more than 5%.
3984	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%.
3985	POLYETHYLENE	E	
3986	POLYGALA CHINENSIS	A, H	
3987	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.
3988	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
3989	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
3990	POLYGLYCERYL-10 PENTASTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3991	POLYGLYCERYL-2 CAPRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. The concentration in the medicine must not be more than 0.5%.
3992	POLYGLYCERYL-2 DIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3.0%.
3993	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3994	POLYGLYCERYL-2 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 3%.
3995	POLYGLYCERYL-2 ISOSTEARATE	E	Polyglyceryl-2 isostearate must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin or in the eye. The concentration in the medicine must be no more than 2.5%.
3996	POLYGLYCERYL-2 TRIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When the concentration of polyglyceryl-2 triisostearate is greater than 3%, the medicine must not be intended for use on damaged skin. The concentration in the medicine must not be more than 5%.
3997	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.

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3998	POLYGLYCERYL-3 BEESWAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.
3999	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4000	POLYGLYCERYL-3 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4001	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%.
4002	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%.
4003	POLYGLYCERYL-3 POLYRICINOLEATE	E	
4004	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIMER DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.

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4005	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%.
4006	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%.
4007	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
4008	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%.
4009	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
4010	POLYGONATUM MULTIFLORUM	A, H	
4011	POLYGONATUM OFFICINALE	A, H	
4012	POLYGONATUM SIBIRICUM	A, E, H	
4013	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%.
4014	POLYGONUM BISTORTA	A, H	

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4015	POLYGONUM ODORATUM	A, H	
4016	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
4017	POLYISOBUTYLENE	E	Only for use when the dosage form is 'chewing gum'. Must comply with: a) the Polyisobutylene monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia National Formulary, as in force or existing from time to time.
4018	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
4019	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%.
4020	POLYMETHACRYLIC ACID	E	
4021	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%.
4022	POLYMETHYLSILSESQUIOXAN E	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4023	POLYPORUS UMBELLATUS	A, H	
4024	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
4025	POLYPROPYLENE GLYCOL	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
4026	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
4027	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4028	POLYQUATERNIUM-22	E	Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
4029	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
4030	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.

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4031	POLYQUATERNIUM-37	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2.5%.</p>
4032	POLYQUATERNIUM-4	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 0.4%.</p>
4033	POLYQUATERNIUM-44	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>
4034	POLYQUATERNIUM-51	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>
4035	POLYQUATERNIUM-7	E	<p>Only for use in topical medicines for dermal application.</p>
4036	POLYSILICONE-11	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 2.1%</p>
4037	POLYSILICONE-14	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 of Polysilicone-14 must be no more than 1%.
4038	POLYSILICONE-15	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4039	POLYSILICONE-2	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.13%.</p>
4040	POLYSORBATE 20	E	
4041	POLYSORBATE 40	E	
4042	POLYSORBATE 60	E	
4043	POLYSORBATE 65	E	
4044	POLYSORBATE 80	E	
4045	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4046	POLYSTYRENE	E	Only for use as part of an adhesive in topical medicines for dermal application.

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4047	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%.
4048	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.
4049	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%.
4050	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4051	POLYVINYL ACETATE PHTHALATE	E	
4052	POLYVINYL ALCOHOL	E	
4053	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4054	POMEGRANATE	E	
4055	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4056	PONCIRUS TRIFOLIATA	A, H	When used internally, oxedrine is a mandatory component of <i>Poncirus trifoliata</i> .

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			The quantity of Oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4057	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%.
4058	PONTEDERIA CRASSIPES	A, H	
4059	POPPY SEED	E, H	
4060	POPPY SEED OIL	E, H	
4061	POPULUS ALBA	A, H	
4062	POPULUS BALSAMIIFERA	A, E, H	
4063	POPULUS CANDICANS	A, H	
4064	POPULUS DELTOIDES	A, H	
4065	POPULUS NIGRA	A, H	
4066	POPULUS TREMULA	A, H	
4067	POPULUS TREMULOIDES	A, H	
4068	PORCINE	H	Only for use as an active homoeopathic ingredient.
4069	PORPHYRIDIDIUM 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%.
4070	PORTULACA OLERACEA	A, E, H	
4071	POTABLE WATER	E	
4072	POTASSIUM ACETATE	E	
4073	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4074	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.

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4075	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4076	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4077	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.
4078	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.
4079	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.
4080	POTASSIUM BICARBONATE	E	
4081	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient. The total concentration of potassium bromide in the

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			medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4082	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.
4083	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4084	POTASSIUM CHLORIDE	A, E, H	When for oral use: (a) potassium is a mandatory component of potassium chloride; (b) the medicine requires the following warning statement on the medicine label: - (POTAS1) 'If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and (c) except when the medicine is for use as oral rehydration therapy, the amount of potassium chloride per dosage unit must not be more than 550 mg. Medicines containing potassium chloride for use as oral rehydration therapy, are subject to the following conditions: (a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; (b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the

			<p>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>
4085	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.
4086	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>
4087	POTASSIUM COCOYL HYDROLYSED SOY PROTEIN	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.15%.</p>
4088	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.

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4089	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.
4090	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.
4091	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.
4092	POTASSIUM HYDROXYCITRATE	A, H	
4093	POTASSIUM IODATE	A, H	Iodine is a mandatory component of potassium iodate. The percentage of iodine from potassium iodate should be calculated based on the molecular weight of potassium iodate. When for use in adults, the medicine must contain a daily dose of no more than 505 micrograms of potassium iodate. When for use in children aged 1-3 years, the medicine must contain a daily dose of no more than 337 micrograms of potassium iodate.
4094	POTASSIUM IODIDE	A, E, H	Iodine is a mandatory component of potassium iodide. The percentage of iodine from potassium iodide should be

			<p>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>
4095	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>
4096	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>
4097	POTASSIUM NITRATE	A, H	<p>Only for dental use.</p> <p>The concentration in the medicine must be no more than 5%.</p>
4098	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>

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4099	POTASSIUM PYROPHOSPHATE	E	Only for oral application, dental or topical use. Not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4100	POTASSIUM SORBATE	E	
4101	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%.
4102	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4103	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.
4104	POTATO STARCH	E	
4105	POTENTILLA ANSERINA	A, H	
4106	POTENTILLA CHINENSIS	A, H	
4107	POTENTILLA DISCOLOR	A, H	
4108	POTENTILLA ERECTA	A, E, H	
4109	POTENTILLA REPTANS	A, H	
4110	POTERIUM OFFICINALE	A, E, H	
4111	POTERIUM SANGUISORBA	A, H	

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4112	POVIDONE	E	
4113	POWDERED CELLULOSE	E	
4114	PPG-1-PEG-9 LAURYL GLYCOL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4115	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%.
4116	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%.
4117	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%.
4118	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%.
4119	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.

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4120	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%.
4121	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4122	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%.
4123	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4124	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%.
4125	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4126	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4127	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4128	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

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			medicine must be no more than 5%.
4129	PREGELATINISED MAIZE STARCH	E	
4130	PREGELATINISED POTATO STARCH	E	
4131	PREGELATINISED RICE STARCH	E	
4132	PREGELATINISED STARCH	E	
4133	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4134	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%.
4135	PRICKLY ASH BARK DRY	A, H	
4136	PRICKLY ASH BARK POWDER	A, H	
4137	PRIMULA VERIS	A, E, H	
4138	PRIMULA VULGARIS	A, E, H	
4139	PRINSEPIA UNIFLORA	A, H	
4140	PROBOSCIDEA PARVIFLORA	A, H	
4141	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%.
4142	PROLINE	A, E	
4143	PROPAN-1-OL	E	Only for use in:

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			<p>- topical medicines for dermal application; or</p> <p>- in combination with other permitted ingredients as a flavour proprietary excipient formulation. The concentration of propan-1-ol in the medicine must not be more than 18%.</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>
4144	PROPANE	E	Only for use as an excipient propellant ingredient.
4145	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>
4146	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>
4147	PROPIONALDEHYDE	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>
4148	PROPIONIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4149	PROPIONYLLEVOCARNITINE HYDROCHLORIDE	A, H	
4150	PROPOLIS	A, E	<p>Lead is a mandatory component of Propolis.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>

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4151	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: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4152	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: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4153	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: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4154	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: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4155	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>

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			<p>When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4156	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>
4157	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>
4158	PROPYL GALLATE	E	
4159	PROPYL HYDROXYBENZOATE	E	
4160	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4161	PROPYLENE GLYCOL	E	
4162	PROPYLENE GLYCOL ALGINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4163	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%.
4164	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%.
4165	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4166	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4167	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4168	PROPYLENE GLYCOL ISOCETETH-3 ACETATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4169	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4170	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.

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4171	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4172	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4173	PROSOPIS JULIFLORA	A, H	
4174	PROTEASE	A	Must be derived from <i>Aspergillus oryzae</i> or <i>Aspergillus niger</i> .
4175	PROTEIN HYDROLYSATE	E	
4176	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%.
4177	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%.
4178	PRUNELLA VULGARIS	A, H	
4179	PRUNUS AFRICANA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus africana</i> . The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4180	PRUNUS ARMENIACA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of

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			<p>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>
4181	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>
4182	PRUNUS CERASIFERA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4183	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>
4184	PRUNUS DOMESTICA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica.</p>

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			<p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4185	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>
4186	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>
4187	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>

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4188	PRUNUS LAUROCERASUS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus laurocerasus</i>.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4189	PRUNUS MUME	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus mume</i>.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4190	PRUNUS PERSICA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus persica</i>.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4191	PRUNUS SALICINA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus salicina</i>.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4192	PRUNUS SEROTINA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus serotina</i>.</p>

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			<p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4193	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 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4194	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4195	PSEUDOCYDONIA SINENSIS	A, H	
4196	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4197	PSEUDOTSUGA MENZIESII	A, H	
4198	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4199	PSIDIUM GUAJAVA	A, E, H	
4200	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4201	PSYLLIUM HUSK DRY	A, H	<p>When a dose for children is stated, the following warning statement is required on the label:</p> <p>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</p>
4202	PSYLLIUM HUSK POWDER	A, E, H	When a dose for children is stated, the following warning statement is required on the label:

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			- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4203	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).
4204	PTELEA TRIFOLIATA	A, H	
4205	PTEROCARPUS MARSUPIUM	A, H	
4206	PTEROCARPUS SANTALINUS	A, E, H	
4207	PUERARIA LOBATA	A, E, H	
4208	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4209	PULLULAN	E	
4210	PUMICE	E	
4211	PUMPKIN	E	
4212	PUMPKIN SEED OIL	E, H	
4213	PUNICA GRANATUM	A, E, H	
4214	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4215	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).
4216	PURIFIED SILICEOUS EARTH	E, H	
4217	PURIFIED TALC	E	
4218	PURIFIED WATER	E	
4219	PVM/MA COPOLYMER	E	
4220	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.

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4221	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4222	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4223	PYRETHRINS	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 10%.</p> <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>
4224	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>
4225	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</p>

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			statement is required on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
4226	PYRIDOXINE HYDROCHLORIDE	A, E, H	<p>When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of pyridoxine hydrochloride.</p> <p>The percentage of pyridoxine from pyridoxine hydrochloride should be calculated based on the molecular weight of pyridoxine hydrochloride.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <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</p>

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			experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'
4227	PYROGLUTAMIC ACID	E	
4228	PYROLA DECORATA	A, H	
4229	PYROLIGNEOUS ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4230	PYRROSIA LINGUA	A, H	
4231	PYRROSIA PETIOLOSA	A, H	
4232	PYRROSIA SHEARERI	A, H	
4233	PYRUS COMMUNIS	A, E, H	Beta-arbutin is a mandatory component of <i>Pyrus communis</i> . When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.

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4234	PYRUS PYRIFOLIA	A, H	<p>Beta-arbutin is a mandatory component of <i>Pyrus pyrifolia</i>.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
4235	PYRUVIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4236	QUASSIA	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4237	QUASSIA AMARA	A, E, H	
4238	QUASSIA WOOD JAMAICAN DRY	A, H	

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4239	QUASSIA WOOD JAMAICAN POWDER	A, H	
4240	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4241	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4242	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4243	QUATERNIUM-52	E	Only for use in wash-on/wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. Not be used in medicines in which N-nitroso compounds may be formed.
4244	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%.
4245	QUERCETIN	A	
4246	QUERCETIN DIHYDRATE	A	
4247	QUERCUS ACUTISSIMA	A, H	
4248	QUERCUS ALBA	A, E, H	
4249	QUERCUS PALUSTRIS	A, H	
4250	QUERCUS ROBUR	A, H	
4251	QUERCUS RUBRA	A, H	
4252	QUERCUS VIRGINIANA	A, H	
4253	QUILLAIA DRY	A, H	
4254	QUILLAIA POWDER	A, E, H	
4255	QUILLAIA SAPONARIA	A, H	
4256	QUINCE	E	

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4257	QUININE ARSENITE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>Quinine is a mandatory component of Quinine arsenite.</p> <p>The maximum recommended daily dose must be no more than 50 mg of quinine.</p>
4258	QUININE SULFATE DIHYDRATE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>Quinine is a mandatory component of quinine sulfate dihydrate.</p> <p>The maximum recommended daily dose must be no more than 50 mg of quinine.</p>
4259	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4260	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4261	QUISQUALIS INDICA	A, H	
4262	R-ALPHA LIPOIC ACID	A	
4263	RACEMENTHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
4264	RACEMIC CAMPHOR	E, H	<p>Only for use as an active homoeopathic or excipient ingredient.</p> <p>In solid and semi solid preparations, the concentration of</p>

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

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			<p>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); - (NTAKEN) 'Not to be taken'; <p>and</p> <ul style="list-style-type: none"> - (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). <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must not be more than 25 millilitres.</p>
4265	RADISH	E	
4266	RAISIN JUICE CONCENTRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4267	RANUNCULUS BULBOSUS	A, H	
4268	RANUNCULUS FICARIA	A, H	
4269	RANUNCULUS TERNATUS	A, H	
4270	RAPE SEED OIL	A, E, H	<p>Allyl isothiocyanate is a mandatory component of rape seed oil when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more</p>

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			than 10 mg/kg or 10 mg/L or 0.001%.
4271	RAPHANUS SATIVUS	A, H	
4272	RASPBERRY	E	
4273	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%.
4274	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%.
4275	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%.
4276	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%.
4277	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%.

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4278	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%.
4279	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%.
4280	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%.
4281	RED 27 ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. The concentration in the medicine must be no more than 0.5%.
4282	RED ANT	H	Only for use as an active homoeopathic ingredient.
4283	RED CLOVER FLOWER DRY	A, H	
4284	RED CLOVER FLOWER POWDER	A, H	
4285	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4286	RED DEER	A	
4287	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4288	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4289	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.

4290	REFINED BUGLOSSOIDES ARVENSIS SEED OIL	A	<p>Only to be used in a medicine where Phytolove Pty Ltd (Client ID 80651), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 3 July 2025.</p> <p>Stearidonic acid is a mandatory component of refined Buglossoides arvensis seed oil.</p> <p>The route of administration for medicines that contain refined Buglossoides arvensis seed oil must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 500 mg of stearidonic acid.</p> <p>The following warning statement (or words to that effect) is required on the medicine label:</p> <p>- (NTAKEN3) 'Not to be taken by children under 3 years old'.</p>
4291	REHMANNIA GLUTINOSA	A, E, H	
4292	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>
4293	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</p>

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			medicine must be no more than 5%.
4294	RESORCINOL DIMETHYLETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4295	RESVERATROL	A	Only permitted for use in medicines that are for oral routes of administration. The maximum recommended daily dose of the medicine must not contain more than 150 milligrams of resveratrol. The following warning statements are required on the medicine label: - (RESVER) 'Resveratrol may affect the way some medicines work, including Warfarin. Consult your health professional before taking with other medicines (or words to that effect).'; - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)'; and - (CHILD2) 'Not suitable for children'.
4296	RETINOL	A, E	Vitamin A is a mandatory component of retinol. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.

			<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.’
4297	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</p>

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			<p>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.’
4298	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</p>

			<p>warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</p>
4299	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4300	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%.
4301	RHAMNUS CATHARTICA	A, H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the

medicine requires the following warning statements on the medicine label:

- (CHILD3) 'Use in children under 12 years is not recommended';
 - (LAX2) 'Prolonged use may cause serious bowel problems';
- and

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

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

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

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

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

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

- (CHILD3) 'Use in children under 12 years is not recommended';
 - (LAX1) 'Drink plenty of water' (or words to that effect); and
 - (LAX2) 'Prolonged use may cause serious bowel problems'.
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4302	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'; <p>and</p> <ul style="list-style-type: none">- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none">- (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none">- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and- (LAX4) 'This product may have laxative effect'. <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as</p>
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			<p>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'.
4303	RHATANY ROOT DRY	A, H	
4304	RHATANY ROOT POWDER	A, H	
4305	RHEUM OFFICINALE	A, E, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum officinale.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect).

			<p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4306	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

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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’.

4307	RHEUM RHAPONTICUM	A, E, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory
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component of Rheum
rhaponticum.

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

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

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

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

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

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

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

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

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

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

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

4308	RHEUM TANGUTICUM	A, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum tanguticum.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none">- (CHILD3) 'Use in children under 12 years is not recommended';- (LAX2) 'Prolonged use may cause serious bowel problems'; and- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none">- (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p>
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			<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	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4310	RHODINOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
4311	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>

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4312	RHODIOLA ROSEA	A	Only for use in oral medicines. Only available for use when the plant preparation is dry root powder, dry root powder as an aqueous extract or dry root powder as a hydroethanolic extract with no more than 70% ethanol v/v.
4313	RHODODENDRON AUREUM	A, H	
4314	RHODODENDRON FERRUGINEUM	A, H	Beta-arbutin is a mandatory component of Rhododendron ferrugineum. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4315	RHODODENDRON GROENLANDICUM	A, H	
4316	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4317	RHUBARB	E, H	When the route of administration is oral, Hydroxyanthracene

derivatives is a mandatory component of Rhubarb.

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

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

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

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

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

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

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

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

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

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

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

4318	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'; <p>and</p> <ul style="list-style-type: none">- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none">- (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p>
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			<p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4319	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</p>

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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	RHUS AROMATICA	A, E, H	
4321	RHUS CHINENSIS	A, H	
4322	RHUS GLABRA	A, E, H	
4323	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4324	RIBES GROSSULARIA	A, E, H	
4325	RIBES NIGRUM	A, E, H	
4326	RIBOFLAVIN	A, E	
4327	RIBOFLAVIN SODIUM PHOSPHATE	A, E	

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

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4346	ROSA CYMOSA	A, E, H	
4347	ROSA EGLANTERIA	A, E, H	
4348	ROSA GALLICA	A, E, H	
4349	ROSA LAEVIGATA	A, E, H	
4350	ROSA MULTIFLORA	A, E, H	
4351	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%.
4352	ROSA RUGOSA	A, E, H	
4353	ROSA VILLOSA	A, E, H	
4354	ROSA X CENTIFOLIA	A, E, H	
4355	ROSA X DAMASCENA	A, E, H	
4356	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%.
4357	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%.
4358	ROSE FRUIT FRESH	A, E, H	
4359	ROSE HIP	E	
4360	ROSE OIL	A, E, H	
4361	ROSE OXIDE	E	Permitted for use only in combination with other permitted

			<p>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>
4362	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>
4363	ROSMARINUS OFFICINALIS	A, E, H	<p>Camphor and cineole are mandatory components of Rosmarinus officinalis.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p> <p>When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres.</p> <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to</p>

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25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.

4364	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> <p>- (CHILD2) 'Not suitable for children'</p> <p>- (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</p>
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			rare cases fatalities, especially in asthma and allergy sufferers'.
4365	ROYAL JELLY FRESH	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4366	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'.
4367	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4368	RUBIA CORDIFOLIA	A, H	
4369	RUBIA TINCTORUM	A, H	
4370	RUBUS CHINGII	A, H	

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4371	RUBUS CORCHORIFOLIUS	A, H	
4372	RUBUS COREANUS	A, E, H	
4373	RUBUS FRUTICOSUS	A, E, H	
4374	RUBUS IDAEUS	A, E, H	
4375	RUBUS OCCIDENTALIS	A, E, H	
4376	RUBUS PARVIFOLIUS	A, H	
4377	RUBUS ROSIFOLIUS	A, H	
4378	RUDBECKIA HIRTA	A, H	
4379	RUE OIL	A, H	
4380	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%.
4381	RUMEX ACETOSA	A, H	
4382	RUMEX ACETOSELLA	A, H	
4383	RUMEX CONGLOMERATUS	A, H	
4384	RUMEX CRISPUS	A, E, H	
4385	RUMEX PULCHER	A, H	
4386	RUMEX SCUTATUS	A, H	
4387	RUSCUS ACULEATUS	A, H	
4388	RUTA GRAVEOLENS	A, E, H	
4389	RUTOSIDE	A, E	
4390	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4391	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.
4392	S-ISOPROPYL 3-METHYLTHIOCRONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4393	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.
4394	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%.
4395	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%.
4396	SACCHARIN	E	
4397	SACCHARIN SODIUM	E	
4398	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4399	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4400	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.

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			The concentration in the medicine must be no more than 1%.
4401	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4402	SACCHARUM OFFICINARUM	A, E, H	
4403	SAFFLOWER OIL	A, E, H	
4404	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4405	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%.
4406	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%.
4407	SAGE OIL DALMATIAN	A	Thujone is a mandatory component of Sage oil dalmatian. The concentration of thujone in the medicine must be no more than 4%. When the concentration of Sage oil dalmatian in the medicine is more than 10% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert and child resistant closure must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'

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4408	SAGE OIL SPANISH	A, E, H	
4409	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%.
4410	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%.
4411	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4412	SALIX ALBA	A, E, H	
4413	SALIX DAPHNOIDES	A, H	
4414	SALIX DISCOLOR	A, H	
4415	SALIX FRAGILIS	A, H	
4416	SALIX NIGRA	A, H	
4417	SALIX PURPUREA	A, H	
4418	SALSOLA KALI	A, H	
4419	SALVIA CHINENSIS	A, H	
4420	SALVIA FRUTICOSA	A, H	
4421	SALVIA HISPANICA	A, E, H	
4422	SALVIA LAVANDULAEFOLIA	A, H	
4423	SALVIA MILTIORRHIZA	A, H	
4424	SALVIA OFFICINALIS	A, E, H	Thujone is a mandatory component of Salvia officinalis.

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			The concentration of thujone in the medicine must be no more than 4%.
4425	SALVIA SCLAREA	A, E, H	
4426	SAMBUCUS CANADENSIS	A, H	
4427	SAMBUCUS EBULUS	A, H	
4428	SAMBUCUS NIGRA	A, E, H	
4429	SANDALWOOD OIL EAST INDIAN	A, E, H	
4430	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4431	SANICULA EUROPAEA	A, H	
4432	SANTALUM ALBUM	A, E, H	
4433	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.
4434	SAPINDUS MUKOROSI	A, H	
4435	SAPONARIA OFFICINALIS	A, H	
4436	SAPOSHNIKOVIA DIVARICATA	A, H	
4437	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%.
4438	SARGASSUM FUSIFORME	A, H	Iodine is a mandatory component of Sargassum fusiforme. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.

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			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
4439	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>
4440	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>
4441	SATUREIA HORTENSIS	A, H	
4442	SATUREIA MONTANA	A, H	
4443	SAUROPUS SPATULIFOLIUS	A, H	
4444	SAURURUS CHINENSIS	A, H	
4445	SAUSSUREA COSTUS	A, H	
4446	SAVORY OIL SUMMER	A, H	
4447	SAXIFRAGA GRANULATA	A, E, H	
4448	SAXIFRAGA STOLONIFERA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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			The concentration in the medicine must not be more than 0.0816%.
4449	SCAPHIUM SCAPHIGERUM	A, H	
4450	SCHEFFLERA HEPTAPHYLLA	A, H	
4451	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4452	SCHINUS MOLLE	A, H	
4453	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%.
4454	SCHISANDRA CHINENSIS	A, E, H	
4455	SCHIZONEPETA TENUIFOLIA	A, E, H	
4456	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%.
4457	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%.
4458	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

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			medicine must be no more than 1%.
4459	SCLERANTHUS ANNUUS	A, H	
4460	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4461	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%.
4462	SCROPHULARIA NINGPOENSIS	A, H	
4463	SCROPHULARIA NODOSA	A, H	
4464	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4465	SCUTELLARIA BAICALENSIS	A, E, H	
4466	SCUTELLARIA BARBATA	A, H	
4467	SCUTELLARIA LATERIFLORA	A, E, H	
4468	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%.
4469	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%.
4470	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%.

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4471	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.
4472	SEDUM ACRE	A, H	
4473	SELAGINELLA TAMARISCINA	A, H	
4474	SELENICEREUS GRANDIFLORUS	A, E, H	
4475	SELENIUM	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine contains selenium which is toxic in high doses.</p> <p>A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'</p>
4476	SELENOCYSTEINE	A	<p>Selenium is a mandatory component of Selenocysteine for oral and sublingual use.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine contains selenium which is toxic in high doses.</p> <p>A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.'</p>

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4477	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>
4478	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4479	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>
4480	SEMOLINA	E	
4481	SEMPERVIVUM TECTORUM	A, H	
4482	SENEGA ROOT DRY	A, H	
4483	SENEGA ROOT POWDER	A, H	
4484	SENNA ALEXANDRINA	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna alexandrina.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p>

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

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

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

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

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

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

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

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

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

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

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

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

4485	SENNA FRUIT ALEXANDRIAN DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; <p>and</p> <ul style="list-style-type: none"> - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as</p>
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			<p>laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4486	SENNA FRUIT ALEXANDRIAN POWDER	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p>

			<p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)']; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4487	SENNA FRUIT TINNEVELLY DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare</p>

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professional before taking this product' (or words to that effect).

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

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

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

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

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

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

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

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

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

4488	SENNA FRUIT TINNEVELLY POWDER	A, H	When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:
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- (CHILD3) 'Use in children under 12 years is not recommended';

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

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

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

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

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

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

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

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

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

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

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

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4489	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'; <p>and</p> <ul style="list-style-type: none">- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none">- (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none">- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]';- (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</p>
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			<p>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'.
4490	SENNA LEAF POWDER	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Leaf Powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; <p>and</p> <ul style="list-style-type: none"> - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires</p>

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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'.

4491	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> <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</p>
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		<p>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 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	<p>SENNA TORA</p> <p>A, H</p>	<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</p>

warning statements on the medicine label:

- (CHILD3) 'Use in children under 12 years is not recommended';
 - (LAX2) 'Prolonged use may cause serious bowel problems';
- and

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

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

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

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

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

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

- (CHILD3) 'Use in children under 12 years is not recommended';
 - (LAX1) 'Drink plenty of water' (or words to that effect); and
 - (LAX2) 'Prolonged use may cause serious bowel problems'.
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4493	SEPIA	H	Only for use as an active homoeopathic ingredient. The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
4494	SEQUOIA SEMPERVIRENS	A, H	
4495	SEQUOIADENDRON GIGANTEUM	A, H	
4496	SERENOA REPENS	A, H	
4497	SERINE	A, E	
4498	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4499	SESAME OIL	A, E, H	
4500	SESAMUM INDICUM	A, E, H	
4501	SETARIA ITALICA	A, H	
4502	SHARK CALCIUM CHONDROITIN SULFATE	A	
4503	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)
4504	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%.

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4505	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4506	SHARK SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
4507	SHARK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of Shark-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use.

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			<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>
4508	SHEA BUTTER	E	
4509	SHEA BUTTER ETHYL ESTERS	E	<p>Shea butter ethyl esters must:</p> <p>(a) Only be used in topical medicines for dermal application; and</p> <p>(b) Not be included in medicines intended for use on broken skin.</p> <p>The total concentration of shea butter ethyl esters in the medicine must not be more than 30%.</p>
4510	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4511	SHELLAC	E	
4512	SHEPHERD'S PURSE HERB DRY	A, H	
4513	SHEPHERD'S PURSE HERB POWDER	A, H	
4514	SHERRY WINE	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>
4515	SIGESBECKIA ORIENTALIS	A, E, H	

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4516	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%.
4517	SILICA DIMETHYL SILYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4518	SILICA SILYLATE	E	Only for use in topical medicines for dermal application.
4519	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4520	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4521	SILICONE QUATERNIUM-8	E	Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%. The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect).
4522	SILVER	H	Only for use as an active homoeopathic ingredient.

			<p>When for external use, the total concentration of silver in the medicine must not be more than 1%.</p> <p>When for oral use:</p> <p>(a) the total concentration of silver in the medicine must not be more than 0.3%; and</p> <p>(b) the following warning statement is required on the medicine label:</p> <p>- ‘Overuse may stain skin or mouth.’ (or words to that effect).</p>
4523	SILVER BOROSILICATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine should be no more than 0.6%.</p> <p>Silver is a mandatory component of Silver borosilicate when the route of administration is topical.</p> <p>The concentration of silver in the medicine must be no more than 1%.</p>
4524	SILVER NITRATE	H	<p>Only for use as an active homoeopathic ingredient.</p>
4525	SILYBUM MARIANUM	A, E, H	
4526	SIMABA CEDRON	A, H	
4527	SIMETHICONE	E	
4528	SIMMONDSIA CHINENSIS	A, E, H	
4529	SINAPIS ALBA	A, H	<p>Allyl isothiocyanate is a mandatory component of Sinapis alba when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>

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4530	SINAPIS ARVENSIS	A, H	
4531	SINOMENIUM ACUTUM	A, H	
4532	SIPHONESTEGIA CHINENSIS	A, H	
4533	SIRAITIA GROSVENORII	A, E, H	
4534	SISYMBRIUM OFFICINALE	A, H	
4535	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>
4536	SKIPJACK-LIVER OIL	A, E	<p>Vitamin A and Colecalciferol are mandatory components of Skipjack-liver oil.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p>

			<p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth 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>
4537	SLIPPERY ELM BARK DRY	A, H	
4538	SLIPPERY ELM BARK POWDER	A, E, H	
4539	SMILAX ARISTOLOCHIIFOLIA	A, H	
4540	SMILAX CHINA	A, H	
4541	SMILAX GLABRA	A, H	
4542	SMILAX OFFICINALIS	A, E, H	
4543	SMILAX ORNATA	A, E, H	
4544	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>
4545	SODIUM ACETATE	E	
4546	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>

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			The concentration in the medicine must be no more than 1%.
4547	SODIUM ACID CITRATE	A, E, H	When sodium acid citrate is used as an active ingredient, only for use in oral medicines.
4548	SODIUM ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.8%.
4549	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).
4550	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).
4551	SODIUM ALGINATE	E	
4552	SODIUM ASCORBATE	A, E, H	
4553	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

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			the medicine must be no more than 0.5%.
4554	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%.
4555	SODIUM BENZOATE	E	
4556	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
4557	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4558	SODIUM BICARBONATE	A, E	When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms. Medicines containing sodium bicarbonate for use as oral rehydration therapy are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.' c) the following warning statements are required on the medicine label:

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			<p>- (UOAD) 'Use only as directed.'</p> <p>- (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice (or words to that effect).'</p> <p>- (DIAR3) 'If diarrhoea persists, seek medical advice.'</p>
4559	SODIUM BISULFITE	E	
4560	SODIUM BROMIDE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>The total concentration of sodium bromide in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
4561	SODIUM BUTYRATE	A, E	<p>The route of administration for medicines that contain sodium butyrate must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 1200 mg sodium butyrate.</p> <p>The following warning statement (or words to the same effect) is required on the medicine label:</p> <p>- (ADULT) 'Adults only'.</p>
4562	SODIUM C14-16 OLEFIN SULFONATE	E	<p>Only for use in topical medicines for dermal application.</p>
4563	SODIUM CALCIUM EDETATE	E	<p>When for oral use, sodium is a mandatory component of sodium calcium edetate.</p> <p>Sodium calcium edetate must only be included in medicines when:</p> <p>(a) the route of administration is limited to topical for dermal use;</p> <p>or</p>

			(b) in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of sodium calcium edetate in the medicine must not exceed 0.32%. The total concentration of flavour proprietary excipient formulations containing sodium calcium edetate must not be more than 5% of the total medicine.
4564	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4565	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.
4566	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.
4567	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%.
4568	SODIUM CARRAGEENAN	E	
4569	SODIUM CASEINATE	E	Permitted for use only in combination with other permitted

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			<p>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>
4570	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4571	SODIUM CHLORIDE	A, E, H	
4572	SODIUM CHONDROITIN SULFATE	A, E	<p>When used as an excipient ingredient:</p> <p>a) only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye;</p> <p>b) the concentration in the medicine must not be more than 0.001%.</p> <p>When used as an active ingredient:</p> <p>a) the route of administration must only be oral;</p> <p>b) the maximum daily dose must not provide more than 1,200 mg of sodium chondroitin sulfate;</p> <p>c) the following statements must be included on the medicine label:</p> <p>- (ADULT) 'Adults only' (or words to that effect);</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).</p>
4573	SODIUM CITRATE	A, E	When for use as an active ingredient, only for oral use.
4574	SODIUM CITRATE DIHYDRATE	A, E	When for use as an active ingredient, only for oral use.

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4575	SODIUM COCO PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
4576	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4577	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4578	SODIUM CYCLAMATE	E	
4579	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4580	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%.
4581	SODIUM DODECYLBENZENESULFONAT E	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4582	SODIUM ERYTHORBATE	E	
4583	SODIUM ETHYL HYDROXYBENZOATE	E	
4584	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>
4585	SODIUM FUMARATE	E	
4586	SODIUM HYALURONATE	A, E	<p>When for use as an excipient ingredient, sodium hyaluronate must only be used in medicines with a topical route of administration for dermal application.</p> <p>When for use as an active ingredient:</p> <p>(a) the molecular mass of sodium hyaluronate must be between 600 and 1600 kilodaltons; and</p> <p>(b) sodium hyaluronate must only be used in medicines when the route of administration is limited to:</p> <p>(i) topical for dermal application; or</p> <p>(ii) oral.</p> <p>When for use in a topical medicine for dermal application the concentration of sodium hyaluronate in the medicine must not exceed 2.0%.</p>

			<p>When for use as an active ingredient and the route of administration is oral:</p> <p>(a) the maximum recommended daily dose must not provide more than 200 milligrams sodium hyaluronate;</p> <p>(b) the recommended duration of use of the medicine must be limited to three months; and</p> <p>(c) the following warning statements (or words to the same effect) are required on the medicine label :</p> <p>- (ADULT) 'Adults only'; and</p> <p>- (PREGNT) ' Not recommended for use by pregnant and lactating women'.</p>
4587	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4588	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>
4589	SODIUM HYDROXYCITRATE	A	
4590	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>
4591	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.

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4592	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of sodium hypochlorite. The concentration of chlorine in the medicine must not be more than 4%.
4593	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4594	SODIUM LACTATE	E	
4595	SODIUM LAURETH SULFATE	E	
4596	SODIUM LAUROAMPHOACETATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4597	SODIUM LAUROYL LACTYLATE	E	Sodium lauroyl lactylate must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin or in the eye. The concentration in the medicine must be no more than 0.2%.
4598	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%.
4599	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4600	SODIUM LAURYL PHOSPHATE	E	

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4601	SODIUM LAURYL SULFATE	E	
4602	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4603	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4604	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%.
4605	SODIUM METABISULFITE	E	
4606	SODIUM METAPHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must not be more than 0.1%.
4607	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine must be no more than 2%.
4608	SODIUM METHYL HYDROXYBENZOATE	E	
4609	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.

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4610	SODIUM MONOFLUOROPHOSPHATE	A	<p>Fluoride is a mandatory component of sodium monofluorophosphate.</p> <p>The route of administration must be limited to dental.</p> <p>The dosage form must be limited to pastes, powders and/or gels for dental hygiene.</p> <p>When sodium monofluorophosphate is used as an active ingredient, it is subject to the following conditions:</p> <p>(a) only for use in combination with at least one other active ingredient; and</p> <p>(b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg.</p> <p>When the concentration of fluoride ion is more than 1000 mg/kg, the following warning statements are required on the medicine label:</p> <p>- (DNTSW) 'Do not swallow.'</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'</p>
4611	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>
4612	SODIUM NITRATE	H	<p>Only for use as an active homoeopathic ingredient.</p>
4613	SODIUM NONOXYNOL-4 SULFATE	E	<p>Only for use in topical medicines for dermal application.</p>
4614	SODIUM PANTOTHENATE	A, E, H	

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4615	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4616	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 not exceed 3500 mg/kg or 3500 mg/L or 0.35%.</p> <p>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:</p> <ul style="list-style-type: none"> - (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). <p>When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> - (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).

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			<p>When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:</p> <p>- (BORON) 'Contains boron' (or words to that effect).</p> <p>When the medicine is for topical use for dermal application, the following warning statement is required on the label:</p> <p>- (BROKEN) 'Use on unbroken skin only' (or words to that effect).</p>
4617	SODIUM PERCARBONATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 15%.</p>
4618	SODIUM POLYACRYLATE	E	<p>Only for use in topical medicines for dermal application.</p>
4619	SODIUM POLYACRYLATE STARCH	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 1%.</p>
4620	SODIUM POLYMETAPHOSPHATE	E	
4621	SODIUM PROPIONATE	E	
4622	SODIUM PROPYL HYDROXYBENZOATE	E	
4623	SODIUM RNA	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.2%.</p>

4624	SODIUM SELENATE	A, H	<p>Selenium is a mandatory component of sodium selenate.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'</p>
4625	SODIUM 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>
4626	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>

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			- (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.'
4627	SODIUM SELENITE PENTAHYDRATE	A	Selenium is a mandatory component of Sodium selenite pentahydrate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4628	SODIUM SILICATE	E	
4629	SODIUM STARCH GLYCOLLATE	E	
4630	SODIUM STARCH GLYCOLLATE TYPE A	E	
4631	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4632	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%.
4633	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.

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			The concentration in the medicine must be no more than 2.5%.
4634	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4635	SODIUM STEARYL PHTHALAMATE	E	Only for use in medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4636	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4637	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'.
4638	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'.
4639	SODIUM SULFITE	E	
4640	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application.
4641	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.

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			The concentration in the medicine must be no more than 5%.
4642	SOLANUM DULCAMARA	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum dulcamara. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4643	SOLANUM FEROX	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum ferox. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4644	SOLANUM LYCOCARPUM FRUIT EXTRACT	E	Only for use in topical medicines for dermal use and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4645	SOLANUM MELONGENA	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum melongena. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4646	SOLANUM NIGRUM	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum nigrum.

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

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4661	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4662	SORBITAN MONO-OLEATE	E	
4663	SORBITAN MONOLAURATE	E	
4664	SORBITAN MONOSTEARATE	E	
4665	SORBITAN OLEATE	E	
4666	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%.
4667	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%.
4668	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4669	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4670	SORBITAN STEARATE	E	
4671	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4672	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.

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4673	SORBITOL SOLUTION (70 PER CENT) (CRYSTALLISING)	A, E	Sorbitol is a mandatory component of sorbitol solution (70 per cent) (crystallising). When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
4674	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.
4675	SORBUS AUCUPARIA	A, H	
4676	SORGHUM	E	
4677	SORGHUM VULGARE	A, H	
4678	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid. The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2024; and - released for supply before 1 March 2025. (a) The concentration of soy phosphatidylserine in the medicine must be no more than 15%.

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			<p>The requirement specified in paragraph (b) below applies to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. <p>(b) The maximum recommended daily dose of the medicine must not provide more than 300 mg of soy phosphatidylserine.</p>
4679	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	<p>Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder.</p> <p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register before 1 March 2024; and - released for supply before 1 March 2025. <p>(a) The concentration of soy phosphatidylserine in the medicine must be no more than 15%.</p> <p>The requirement specified in paragraph (b) below applies to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. <p>(b) The maximum recommended daily dose of the medicine must not provide more than 300 mg of soy phosphatidylserine.</p>
4680	SOY POLYSACCHARIDE	E	
4681	SOY PROTEIN	E	

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4682	SOY STEROL	E	
4683	SOYA BEAN	E	
4684	SOYA OIL	A, E, H	
4685	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%.
4686	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%.
4687	SPARGANIUM STOLONIFERUM	A, H	
4688	SPARTIUM JUNCEUM	A, H	
4689	SPATHOLOBUS SUBERECTUS	A, H	
4690	SPEARMINT OIL	A, E, H	Menthol is a mandatory component of spearmint oil. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following

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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.

4691	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> <p>ii) the medicine must not deliver more than 25% total menthol</p>
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			<p>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>
4692	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>
4693	SPIGELIA ANTHELMIA	A, H	
4694	SPIGELIA MARILANDICA	A, H	<p>The maximum recommended daily dose must be no more than</p>

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			the equivalent of 1mg of the dry herbal material.
4695	SPIKE LAVENDER OIL	A, E, H	<p>Camphor is a mandatory component of spike lavender oil.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or</p>

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			equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
4696	SPINACH	E	
4697	SPINACIA OLERACEA	A, E, H	
4698	SPIRODELA POLYRRHIZA	A, H	
4699	SPIRULINA	E	
4700	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use as an excipient for oral routes of administration.
4701	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use as an excipient for oral routes of administration.
4702	SPRUCE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4703	SQUALANE	E	Only for use in topical medicines for dermal application.
4704	SQUALENE	A, E	
4705	SQUID OIL	A	Only for use in oral medicines. Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in

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			combination with other ingredients in the medicine and be presented in a therapeutic dosage form for therapeutic use. The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
4706	SQUILL DRY	A, H	
4707	SQUILL INDIAN DRY	A, H	
4708	SQUILL INDIAN POWDER	A, H	
4709	SQUILL POWDER	A, H	
4710	ST JOHN'S WORT DRY EXTRACT QUANTIFIED	A	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4711	ST JOHN'S WORT HERB DRY	A, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4712	ST JOHN'S WORT HERB POWDER	A, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'

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4713	STACHYS OFFICINALIS	A, E, H	
4714	STACHYS PALUSTRIS	A, H	
4715	STACHYURUS HIMALAICUS	A, H	
4716	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%.
4717	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4718	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).
4719	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%.
4720	STARCH SODIUM OCTENYL SUCCINATE	E	
4721	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.

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4722	STEARKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4723	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4724	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4725	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4726	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).
4727	STEARETH-10	E	Only for use in topical medicines for dermal application.
4728	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%.
4729	STEARETH-2	E	Only for use in topical medicines for dermal application.
4730	STEARETH-20	E	Only for use in topical medicines for dermal application.
4731	STEARETH-21	E	Only for use in topical medicines for dermal application.

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4732	STEARETH-5	E	Only for use in topical medicines for dermal application.
4733	STEARIC ACID	E	
4734	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%.
4735	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%.
4736	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4737	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4738	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4739	STEARYL ALCOHOL	E	
4740	STEARYL BEHENATE	E	Only for use as an excipient ingredient for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 3.5% in the final formulation.
4741	STEARYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to

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			<p>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).
4742	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4743	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4744	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>
4745	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4746	STELLARIA CHAMAEJASME	A, H	
4747	STELLARIA DICHOTOMA	A, H	
4748	STELLARIA MEDIA	A, E, H	
4749	STEMONA JAPONICA	A, H	
4750	STEMONA SESSILIFOLIA	A, H	
4751	STENOTAPHRUM SECUNDATUM	A, H	
4752	STEPHANIA TETRANDA	A, H	
4753	STERCULIA	A, H	
4754	STERCULIA TRAGACANTHA	A, H	
4755	STERCULIA URENS	A, H	
4756	STEVIA REBAUDIANA	A, E, H	

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4757	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4758	STILLINGIA SYLVATICA	A, H	
4759	STORAX PREPARED	A, E, H	
4760	STRAWBERRY	E	
4761	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%.
4762	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'.
4763	STREPTOCOCCUS THERMOPHILUS	A	
4764	STROBILANTHES CUSIA	A, H	
4765	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%.

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4766	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4767	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4768	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4769	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%.
4770	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%.
4771	STYPHNOLOBIUM JAPONICUM	A, E, H	
4772	STYRALLYL PROPIONATE	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
4773	STYRAX BENZOIN	A, E, H	
4774	STYRAX OIL	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>
4775	STYRAX PARALLELONEURUM	A, H	
4776	STYRAX TONKINENSIS	A, H	
4777	STYRENE	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> <p>The total concentration of styrene in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
4778	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4779	STYROLYL 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>
4780	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4781	SUCCINIC ACID	E	
4782	SUCRALOSE	E	
4783	SUCROSE	E	
4784	SUCROSE ACETATE ISOBUTYRATE	E	Permitted for use only in combination with other permitted

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			<p>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>
4785	SUCROSE ACETATE PALMITATE STEARATE	E	<p>Only for use in topical medicines for dermal application and not 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>
4786	SUCROSE COCOATE	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>
4787	SUCROSE DISTEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
4788	SUCROSE LAURATE	E	<p>When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate.</p>
4789	SUCROSE OCTAACETATE	E	<p>When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.</p>
4790	SUCROSE PALMITATE	E	<p>Only for use in topical medicines for dermal application.</p>
4791	SUCROSE POLYCOTTONSEEDATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</p>

			<p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (EYE) 'Avoid contact with the eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4792	SUCROSE STEARATE	E	<p>For use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>When for topical use, the concentration in the medicine must be no more than 0.25%.</p> <p>For oral use as a manufacturing aid only.</p> <p>When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit.</p>
4793	SUCROSE TRISTEARATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 2%.</p>
4794	SUDAN III	E	<p>Permitted for use only as a colour for topical use.</p>
4795	SUGAR CANE WAX ALCOHOLS	A, H	<p>The routes of administration for medicines that contain sugar cane wax alcohols must be limited to:</p> <ul style="list-style-type: none"> (a) topical for dermal use; and (b) oral. <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>

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			<p>(a) the maximum recommended daily dose of the medicine must not provide more than:</p> <p>(i) 12 mg of sugar cane wax alcohols for individuals aged less than 18 years; and</p> <p>(ii) 20 mg of sugar cane wax alcohols for individuals aged 18 years and above.</p> <p>(b) The following warning statement (or words to the same effect) is required on the medicine label:</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women'.</p> <p>(c) If the maximum recommended daily dose of the medicine contains 20 mg of sugar cane wax alcohols, the following warning statement is also required on the medicine label:</p> <p>- (ADULTS) 'Adults only'.</p>
4796	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of sugarcane.
4797	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4798	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%.
4799	SULFUR DIOXIDE	E	
4800	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.

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4801	SULFURIC ACID	E, H	<p>Only for use as an active homoeopathic ingredient or excipient ingredient.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
4802	SULFURISED 1-METHYL-4-(1-METHYLETHENYL)-CYCLOHEXENE	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>
4803	SULISOBENZONE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4804	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>

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			- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4805	SUNFLOWER OIL	A, E, H	
4806	SUNFLOWER SEED	E, H	
4807	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4808	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
4809	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4810	SWEDE	E	
4811	SWEET ORANGE OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4812	SWEET POTATO	E	
4813	SWERTIA CHIRATA	A, H	
4814	SWIETENIA MAHOGANI	A, H	
4815	SYAGRUS ROMANZOFFIANA	A, E, H	
4816	SYMPHYOTRICHUM NOVI- BELGII	A, H	
4817	SYMPHYTUM OFFICINALE	H	When used orally as an active homoeopathic ingredient, the

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			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%.
4818	SYMPLOCARPUS FOETIDUS	A, H	
4819	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4820	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.
4821	SYNTHETIC WAX	E	
4822	SYRINGA RETICULATA	A, H	
4823	SYRINGA VULGARIS	A, H	
4824	SYZYGIUM AROMATICUM	A, E, H	When the plant preparation is oil or distillate and the concentration of this oil or distillate in the product is greater than 25%, the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the plant preparation is oil or distillate, the concentration of this oil or distillate in the medicine is greater than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, a child resistant closure and

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			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%.
4825	SYZYGIUM CUMINI	A, H	
4826	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%.
4827	TABEBUIA SERRATIFOLIA	A, E, H	
4828	TADEHAGI TRIQUETRUM	A, H	
4829	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%.
4830	TAGETES MINUTA	A, E, H	
4831	TAGETES OIL	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>
4832	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4833	TALLOW	E	Only for use in topical medicines for dermal application.
4834	TALLOW GLYCERIDES	E	
4835	TAMARINDUS INDICA	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>
4836	TAMARIX APHYLLA	A, H	
4837	TAMARIX CHINENSIS	A, H	
4838	TAMARIX GALLICA	A, H	
4839	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.
4840	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4841	TANACETUM COCCINEUM SUBSP. COCCINEUM	A, H	
4842	TANACETUM PARTHENIUM	A, E, H	

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

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4855	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%.
4856	TAURINE	A, E	
4857	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4858	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'.
4859	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4860	TERMINALIA CATAPPA	A, H	
4861	TERMINALIA CHEBULA	A, H	
4862	TERMINALIA FERDINANDIANA	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2024; and

- released for supply before 1 March 2025.

(a) Only for use when the plant part is fruit flesh, fruit flesh dry or the preparation is as an aqueous extract of the fruit flesh.

(b) When used as an excipient, the ingredient is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye.

(c) When used as an excipient, the concentration in the medicine must be no more than 0.3%.

The requirements specified in paragraphs (d) to (e) below apply to a medicine that contains the ingredient that is:

- listed in the Register on or after 1 March 2024; or

- released for supply on or after 1 March 2025.

(d) When used as an active ingredient:

(i) the plant part must be from fruit flesh or seed only; and

(ii) the plant preparation must be limited to fresh, dry, powder, and extraction preparations with water as the only solvent.

(e) When used as an excipient ingredient:

(i) the route of administration for medicines that contain *Terminalia ferdinandiana* must be limited to topical for dermal use;

(ii) medicines that contain *Terminalia ferdinandiana* are not to be intended for use on damaged skin or in the eye; and

(iii) the concentration of *Terminalia ferdinandiana* in the

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			medicine must not be more than 0.3%.
4863	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>
4864	TERPENE RESIN	E	<p>Terpene resin must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application.</p>
4865	TERPINEN-4-OL	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>
4866	TERPINEOL	E	
4867	TERPINEOL 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</p>

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4868	TERPINOLENE	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>
4869	TERPINYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4870	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>
4871	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</p>

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			medicine must be no more than 1%.
4872	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4873	TERT-BUTYL HYDROQUINONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4874	TERT-BUTYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4875	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%.
4876	TETRACLINIS ARTICULATA	A, E, H	
4877	TETRADECYL AMINOBTYROYLVALYLAMIN 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%.
4878	TETRADIUM RUTICARPUM	A, H	When for internal use, oxedrine is a mandatory component of Tetradium ruticarpum.

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			The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4879	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%.
4880	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%.
4881	TETRAHYDRO PARA-METHYLQUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4882	TETRAHYDRO-6-(3-PENTENYL)-2H-PYRAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4883	TETRAHYDRODIFERULOYLME THANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.

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4884	TETRAHYDROFURFURYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4885	TETRAHYDROGERANYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4886	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%.
4887	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%.
4888	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%.

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4889	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4890	TETRAMETHYL ACETYLOCTAHYDRONAPHTHA LENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4891	TETRAPANAX PAPYRIFER	A, H	
4892	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4893	TETRASODIUM PYROPHOSPHATE	E	
4894	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4895	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4896	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4897	THAPSIA GARGANICA	A, H	
4898	THAUMATIN	E	
4899	THEANINE	A	Only to be used in a medicine where Trans Chem Pty Ltd (Client ID 21878), who applied to have

			<p>the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 March 2026.</p> <p>The route of administration for medicines that contain theanine must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 450 mg of theanine.</p> <p>The following warning statements (or words to the same effect) are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'.
4900	THEASPIRANE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4901	THEMEDA TRIANDRA	A, H	
4902	THEOBROMA CACAO	A, E, H	<p>Caffeine is a mandatory component of Theobroma cacao.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>When for internal use or oral application, the maximum</p>

recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.

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

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

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

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

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

- (CAFFLMT) 'Limit the use of caffeine-containing products
-

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			(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).
4903	THEOBROMA OIL	A, E, H	
4904	THIAMINE	A, E	
4905	THIAMINE HYDROCHLORIDE	A, E	
4906	THIAMINE NITRATE	A, E	
4907	THIOCINEOLE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4908	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%.
4909	THLASPI ARVENSE	A, E, H	
4910	THREONINE	A, E	
4911	THUJA OCCIDENTALIS	A, H	
4912	THUJA PLICATA	A, E, H	
4913	THYME HERB DRY	A, E, H	
4914	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:

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			- (CHILD) 'Keep out of reach of children' (or words to that effect).
4915	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.
4916	THYMOL METHYL ETHER	E	Thymol methyl ether must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of the flavour proprietary excipient formulation containing thymol methyl ether must not be more than 5% of the total medicine.
4917	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).
4918	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4919	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

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			restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4920	THYMUS 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).
4921	THYMUS VULGARIS	A, E, H	When the plant preparation is oil or distillate, and the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4922	THYMUS VULGARIS MIS	A, E, H	When the plant preparation is an oil or distillate, and the concentration of Thymus vulgaris MIS oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres;

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			(b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4923	THYMUS ZYGIS	A, H	When the plant preparation is an oil or a distillate, and the concentration of Thymus zygis oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4924	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4925	TILACTASE	A	Must be derived from <i>Aspergillus oryzae</i> and comply with the relevant USP monograph.
4926	TILIA CORDATA	A, E, H	
4927	TILIA PLATYPHYLLOS	A, E, H	
4928	TILIA TOMENTOSA	A, H	
4929	TILIA X VULGARIS	A, E, H	
4930	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%.

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4931	TIN	H	Only for use as an active homoeopathic ingredient.
4932	TINOSPORA CORDIFOLIA	A, H	
4933	TINOSPORA SINENSIS	A, H	
4934	TITANIUM DIOXIDE	A, E	<p>For use as an active ingredient only in sunscreens for dermal application.</p> <p>The concentration in sunscreens must be no more than 25%.</p> <p>For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration.</p> <p>Not to be included in medicines intended for use in the eye.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4935	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>
4936	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>

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			When for topical use, the concentration in the medicine must be no more than 0.1%
4937	TOCOPHEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4938	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%
4939	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4940	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%.
4941	TOLU BALSAM	A, E, H	
4942	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%.
4943	TOLYL ALDEHYDE	E	Permitted for use only in combination with other permitted

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			<p>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>
4944	TOLYLALDEHYDE GLYCERYLACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4945	TOMATO	E	
4946	TONKA	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
4947	TONKA BEAN EXTRACT	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4948	TONONE	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%.
4949	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4950	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.
4951	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4952	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4953	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4954	TRACHYSPERMUM AMMI	A, E	Only for use in oral medicines when the plant part is fruit or seed. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect). Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

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			medicine must be no more than 5%.
4955	TRAGACANTH	A, E	
4956	TRAMETES VERSICOLOR	A, H	
4957	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4958	TRANS,TRANS-2,4-DECADIEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4959	TRANS,TRANS-2,4-HEXADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 13.5 mg of Trans,Trans-2,4-Hexadienal.
4960	TRANS-1-(2,4,4-TRIMETHYL-2-CYCLOHEXEN-1-YL)-2-BUTEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4961	TRANS-2-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4962	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>
4963	TRANS-2-HEPTEN-1-AL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4964	TRANS-2-HEXENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4965	TRANS-2-HEXENOIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a</p>

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			medicine must be no more than 5%.
4966	TRANS-2-HEXENOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4967	TRANS-2-HEXENYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4968	TRANS-2-HEXENYL PHENYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4969	TRANS-2-HYDROXYCINNAMIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4970	TRANS-2-OCTENAL	E	trans-2-Octenal must only be included in medicines when in combination with other permitted

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			<p>ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing trans-2-octenal must not be more than 1% of the total medicine.</p>
4971	TRANS-2-UNDECENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4972	TRANS-3-HEXENOIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4973	TRANS-4-DECENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
4974	TRANS-8-(1-METHYLETHYL)-1-OXASPIRO(4.5)DECAN-2-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
4975	TRANS-ETHYL 2-OCTENOATE	E	<p>Permitted for use only in combination with other permitted</p>

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			<p>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>
4976	TRANS-METHYL-2-HEXENOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4977	TREACLE	E	<p>When for oral or sublingual use, sucrose is a mandatory component of treacle.</p>
4978	TREEMOSS ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>When included in a medicine for use on the lips the concentration of treemoss absolute must be no more than 0.02%.</p> <p>When for dermal use or use on the hair the concentration of treemoss absolute must be no more than 0.1%</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
4979	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>

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			Liquid Preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. Only able to be used when presented in single use sachets for therapeutic use as an iron supplement.
4980	TREHALOSE DIHYDRATE	E	When for oral use and the quantity of trehalose dihydrate per maximum recommended daily dose exceeds 20 grams, the quantity of trehalose dihydrate must be declared on the label.
4981	TREMELLA FUCIFORMIS	A, H	
4982	TRIACETIN	E	
4983	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4984	TRIADICA SEBIFERA	A, H	
4985	TRIBASIC POTASSIUM PHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of tribasic potassium phosphate. When used in a solid medicine containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid medicine containing this ingredient, the pH of the medicine must be no more than 11.5.
4986	TRIBASIC SODIUM PHOSPHATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.

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4987	TRIBEHENIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4988	TRIBEHENIN PEG-20 ESTERS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4989	TRIBULUS TERRESTRIS	A, E, H	
4990	TRIBUTYL ACETYLCITRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4991	TRICALCIUM PHOSPHATE	E	
4992	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%.
4993	TRICAPRYLYL CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.

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4994	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4995	TRICHLOROMETHYLPHENYLARBINYL 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%.
4996	TRICHODERMA VIRIDE	A, E, H	
4997	TRICHOSANTHES KIRILOWII	A, E, H	
4998	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
4999	TRICYCLODECENYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5000	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%.
5001	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
5002	TRIDECETH-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.

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5003	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%.
5004	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
5005	TRIDECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 23%.
5006	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%.
5007	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
5008	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
5009	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%.
5010	TRIETHYL CITRATE	E	

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5011	TRIETHYLENE GLYCOL	E	
5012	TRIFOLIUM PRATENSE	A, E, H	
5013	TRIFOLIUM REPENS	A, H	
5014	TRIGONELLA FOENUM- GRAECUM	A, E, H	
5015	TRIHYDROXPALMITAMIDOH YDROXYPROPYL MYRISTYL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
5016	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
5017	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
5018	TRIISODECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5019	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%.
5020	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
5021	TRILAURIN	E	Only for use in topical medicines for dermal application.
5022	TRILISA ODORATISSIMA	A, H	
5023	TRILLIUM ERECTUM	A, H	

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5024	TRIMETHOXYCAPRYLYL SILANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.25%.
5025	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%.
5026	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%.
5027	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%.
5028	TRIMETHYLBENZENEPROPANO L	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5029	TRIMETHYLHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5030	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5031	TRIMETHYLPENTANEDIOL/ADI PIC 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%.
5032	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5033	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%.
5034	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%.
5035	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%.
5036	TRIOLEIN	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 0.1%.
5037	TRIOSTEUM PERFOLIATUM	A, H	
5038	TRIOXAUNDECANEDIOIC ACID	E	
5039	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%.
5040	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).
5041	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%.
5042	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.

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5043	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%.
5044	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%.
5045	TRISTEARIN	E	
5046	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.
5047	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.
5048	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%.
5049	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5050	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.

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5051	TROLAMINE SALICYLATE	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 12%.</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).
5052	TROLLIUS CHINENSIS	A, H	
5053	TROMETAMOL	E	
5054	TROMETAMOL HYDROCHLORIDE	E	
5055	TROPAEOLUM MAJUS	A, E, H	
5056	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5057	TROPOLONE	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>
5058	TSUGA CANADENSIS	A, H	
5059	TULIPA EDULIS	A, H	<p>Colchicine is a mandatory component of <i>Tulipa edulis</i>.</p> <p>The concentration of colchicine in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>

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5060	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5061	TURNERA DIFFUSA	A, E, H	<p>Beta-arbutin is a mandatory component of Turnera diffusa.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
5062	TURNIP	E	
5063	TURPENTINE OIL	A, E	<p>Only permitted for use when turpentine oil is derived from sources other than mineral turpentine.</p> <p>The concentration in the medicine must not be more than 25%.</p>
5064	TYPHA ANGUSTIFOLIA	A, H	
5065	TYPHA LATIFOLIA	A, H	
5066	TYPHONIUM GIGANTEUM	A, H	
5067	TYROSINE	A, E	

