

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

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

Note: See sections 5 and 6.

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
3643	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>
3644	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>
3645	PADIMATE O	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 8%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective

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			clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3646	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%.
3647	PAEONIA LACTIFLORA	A, E, H	
3648	PAEONIA OBOVATA	A, H	
3649	PAEONIA SUFFRUTICOSA	A, E, H	
3650	PAEONIA VEITCHII	A, H	
3651	PALIURUS SPINA-CHRISTI	A, H	
3652	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3653	PALM FRUIT OIL	A, E, H	
3654	PALM GLYCERIDES	E	
3655	PALM KERNEL OIL	A, E, H	
3656	PALM TOCOTRIENOLS COMPLEX	A, H	
3657	PALMARIA PALMATA	A, H	
3658	PALMAROSA OIL	A, E, H	
3659	PALMIDROL	A	Only to be used in a medicine where Pharmako Biotechnologies Pty Ltd (Client ID 62358), 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 02 December 2021.

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			<p>Only permitted for use in medicines limited to oral routes of administration.</p> <p>The maximum recommended daily dose of the medicine must not contain more than 600mg of palmidrol.</p> <p>The following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use' (or words to that effect). - (ADULT) 'Adults only' (or words to that effect) - 'Not to be used for more than 21 consecutive days' (or words to that effect).
3660	PALMITIC ACID	E	
3661	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3662	PALMITOYL DIPEPTIDE-7	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 0.002%.</p>
3663	PALMITOYL HYDROXYPROPYLTRIMONIUM AMYLOPECTIN/GLYCERIN CROSSPOLYMER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.01%</p>

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3664	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%.
3665	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%.
3666	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%.
3667	PANAX GINSENG	A, E, H	
3668	PANAX JAPONICUS	A, H	
3669	PANAX NOTOGINSENG	A, H	
3670	PANAX PSEUDOGINSENG	A, H	
3671	PANAX QUINQUEFOLIUS	A, H	
3672	PANICUM MILIACEUM	A, H	
3673	PANTETHINE	E	Only for use in topical medicines for dermal application.
3674	PANTHENOL	A, E	
3675	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.

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3676	PANTOLACTONE	E	
3677	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3678	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%.
3679	PAPAIN	A, E	
3680	PAPER	E	Only for use in topical medicines for dermal application.
3681	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%.
3682	PARA-CRESOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3683	PARA-CRESYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

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			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3684	PARA-CRESYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3685	PARA-CRESYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3686	PARA-CYMENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3687	PARA-ETHOXYBENZALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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			flavour concentration in a medicine must be no more than 5%.
3688	PARA-ETHYL CRESOXYACETATE	E	Para-ethyl cresoxyacetate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing para-ethyl cresoxyacetate must not be more than 1% of the total medicine.
3689	PARA-ETHYLPHENOL	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The maximum recommended daily dose must contain no more than 0.12 mg of para-ethylphenol. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
3690	PARA-HYDROXY BENZALACETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3691	PARA-HYDROXYBENZOIC ACID	E	
3692	PARA-MENTHA-8-THIOL-3-ONE	E	Permitted for use only in combination with other permitted ingredients as a

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			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%.
3693	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%.
3694	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%.
3695	PARA-METHYL DIMETHYLBENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3696	PARA-PROPYL ANISOLE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3697	PARA-TERT-BUTYLCYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3698	PARA-TERT-BUTYLPHENYL-ALPHA-METHYLHYDROCINNAMIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3699	PARA-TOLUALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3700	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3701	PARAMERIA LAEVI GATA	A, H	
3702	PARIETARIA JUDAICA	A, H	
3703	PARIS POLYPHYLLA	A, H	
3704	PARIS QUADRIFOLIA	A, H	
3705	PARSLEY	E, H	
3706	PARSLEY HERB DRY	A, E, H	
3707	PARSLEY HERB OIL	A, E, H	
3708	PARSLEY HERB POWDER	A, E, H	
3709	PARSLEY SEED OIL	A, E, H	
3710	PARTHENOCISSUS TRICUSPIDATA	A, H	
3711	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.
3712	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%.
3713	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%.

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3714	PASPALUM NOTATUM	A, H	
3715	PASSIFLORA CAERULEA	A, H	
3716	PASSIFLORA EDULIS	E	
3717	PASSIFLORA HERB DRY	A, H	
3718	PASSIFLORA INCARNATA	A, E, H	
3719	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%.
3720	PATENT BLUE V	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3721	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3722	PATRINIA SCABIOSIFOLIA	A, H	
3723	PATRINIA VILLOSA	A, H	
3724	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana. 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 4%. When the medicine is packaged for supply as a divided preparation and is for

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			<p>internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 September 2019; or - is released for supply after 2 March 2021. <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> - was listed in the Register before 2 September 2019; and - is released for supply before 2 March 2021; <p>may comply with the requirements in paragraphs (a) to (e) below.</p> <p>a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.</p> <p>b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>d) When the maximum recommended daily dose of the medicine provides greater than</p>

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			<p>10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' e) 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: <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
3725	PAULLINIA PINNATA	A, H	
3726	PAWPAW	E	
3727	PEA	E	
3728	PEA STARCH	E	
3729	PEACH	E	

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3730	PEANUT	E	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
3731	PEAR	E	
3732	PECAN	E	
3733	PECTIN	A, E	
3734	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%.
3735	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3736	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3737	PEG-12 DILAURATE	E	
3738	PEG-12 DIMETICONE/PPG-20 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3739	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.

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Item	Ingredient name	Purpose	Specific requirements
3740	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3741	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3742	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3743	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%.
3744	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3745	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3746	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3747	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3748	PEG-25 PABA	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines

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			intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3749	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3750	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3751	PEG-35 CASTOR OIL	E	
3752	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3753	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%.

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3754	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3755	PEG-40 CASTOR OIL	E	
3756	PEG-40 HYDROGENATED CASTOR OIL	E	
3757	PEG-40 SORBITAN DIISOSTEARATE	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of PEG-40 sorbitan diisostearate. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3758	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3759	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3760	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3761	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3762	PEG-55 PROPYLENE GLYCOL OLEATE	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.6%.
3763	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3764	PEG-60 ALMOND GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration when used in medicines applied directly to the skin must be no more than 10%. The concentration when used in bath oil medicines must be no more than 30%.
3765	PEG-60 GLYCERYL ISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3766	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3767	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3768	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.

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3769	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3770	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3771	PEG-75 STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3772	PEG-8 CETYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0005%.
3773	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%.
3774	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3775	PEG-8 LAURATE	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. The levels of possible impurities such as ethylene oxide (and related material) must be kept below the level of detection.
3776	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3777	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3778	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%.
3779	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%.
3780	PEG/PPG-18/18 DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.

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3781	PELARGONIUM GRAVEOLENS	A, E, H	
3782	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%.
3783	PELTIGERA CANINA	A, H	
3784	PENICILLIUM EXPANSUM	A, H	
3785	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.
3786	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.

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			The concentration in the medicine must be no more than 0.018%
3787	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%.
3788	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3789	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%.
3790	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%.
3791	PENTASODIUM ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal

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	TETRAMETHYLENE PHOSPHONATE		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%.
3792	PENTYLENE GLYCOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3793	PEPPER BLACK	E, H	
3794	PEPPER OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3795	PEPPER WHITE	E, H	
3796	PEPPERMINT AMERICAN EXT.	E	Menthol is a mandatory component of peppermint american ext. When the medicine is for topical use for dermal application: a) the medicine must not be intended for use in the eye or on damaged skin; b) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; c) the following warning statement is required on the

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>medicine label:</p> <ul style="list-style-type: none"> - (EYE) Avoid contact with eyes (or words to that effect). d) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: <ul style="list-style-type: none"> - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. 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: <ul style="list-style-type: none"> - (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3797	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> <ul style="list-style-type: none"> (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>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>
3798	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>

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Item	Ingredient name	Purpose	Specific requirements
			<p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3799	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>

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Item	Ingredient name	Purpose	Specific requirements
			<p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3800	PEPPERMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a

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Item	Ingredient name	Purpose	Specific requirements
			flavour proprietary excipient formulation or fragrance proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. The total fragrance proprietary excipient formulation in a medicine must be no more 1%. Menthol is a mandatory component of peppermint oil terpeneless. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol

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Item	Ingredient name	Purpose	Specific requirements
			<p>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>
3801	PEPPERMINT OIL TERPENES AND TERPENOIDS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>Menthol is a mandatory component of peppermint oil terpenes and terpenoids.</p> <p>When the medicine is for topical use for dermal application:</p> <p>i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>iv) if the medicine delivers more than 1% total menthol when administered according</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>to the directions for use, the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. <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> <ul style="list-style-type: none"> – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3802	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3803	PERHYDRO-3,6-DIMETHYLBENZO [B] FURAN-2-ONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3804	PERILLA FRUTESCENS	A, E, H	
3805	PERILLALDEHYDE	E	Permitted for use only in

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Item	Ingredient name	Purpose	Specific requirements
			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3806	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>
3807	PERMETHRIN	E	<p>The concentration of in the medicine must be no more than 2%.</p>
3808	PERSEA AMERICANA	A, E, H	
3809	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>
3810	PERSICARIA CHINENSIS	A, H	
3811	PERSICARIA TINCTORIA	A, H	
3812	PERSIMMON	E	
3813	PERU BALSAM	A, E, H	
3814	PERU BALSAM OIL	A, E, H	

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Item	Ingredient name	Purpose	Specific requirements
3815	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>
3816	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>
3817	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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Item	Ingredient name	Purpose	Specific requirements
3818	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.
3819	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%.
3820	PETROSELINUM CRISPUM	A, E, H	
3821	PEUCEDANUM PRAERUPTORUM	A, E, H	
3822	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).
3823	PHALARIS ARUNDINACEA	A, H	
3824	PHALARIS CANARIENSIS	A, H	
3825	PHASEOLUS COCCINEUS	A, H	
3826	PHASEOLUS VULGARIS	A, H	
3827	PELLINUS ROBINIAE	A, E, H	
3828	PELLODENDRON AMURENSE	A, E, H	
3829	PELLODENDRON CHINENSE	A, H	

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Item	Ingredient name	Purpose	Specific requirements
3830	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3831	PHENETHYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3832	PHENETHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3833	PHENETHYL ALCOHOL	E	Permitted for use only: a) in topical medicines for dermal application; and b) for internal use in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation concentration in a medicine must be no more than 5%.

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Item	Ingredient name	Purpose	Specific requirements
3834	PHENETHYL BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3835	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%
3836	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%.
3837	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%.
3838	PHENETHYL ISOVALERATE	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			permitted 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%.
3839	PHENETHYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3840	PHENETHYL SALICYLATE	E	Permitted for use 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	PHENOL	E	Only for use in topical medicines for dermal application. The concentration of phenol in the medicine must be no more than 1%.
3842	PHENOXYACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a

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Item	Ingredient name	Purpose	Specific requirements
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3843	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The concentration of phenoxyethanol in the preparation must not exceed 15%.
3844	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%.
3845	PHENOXYETHYL PARABEN	E	Only for use in topical medicines for dermal application.
3846	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3847	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3848	PHENYLACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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Item	Ingredient name	Purpose	Specific requirements
			<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>
3849	PHENYLACETALDEHYDE DIMETHYL ACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3850	PHENYLACETALDEHYDE GLYCERYLACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3851	PHENYLACETIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3852	PHENYLALANINE	A, E	When for oral ingestion the medicine requires the following warning statement

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Item	Ingredient name	Purpose	Specific requirements
			<p>on the medicine label:</p> <ul style="list-style-type: none"> - (PKU) 'Phenylketonurics are warned that this medicine contains phenylalanine' (or words to that effect). <p>When the medicine contains more than 500mg in the maximum recommended daily dose it requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.
3853	PHENYLBENZIMIDAZOLE SULFONIC ACID	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 4%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <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).
3854	PHENYLETHYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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Item	Ingredient name	Purpose	Specific requirements
3855	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%.
3856	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%.
3857	PHENYLETHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3858	PHENYLETHYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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Item	Ingredient name	Purpose	Specific requirements
3859	PHENYLETHYL METHYLETHYL 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%.
3860	PHENYLETHYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3861	PHENYLETHYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3862	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%.
3863	PHENYLPROPANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Item	Ingredient name	Purpose	Specific requirements
			for use in the eye. The concentration in the medicine must be no more than 0.16%.
3864	PHLEUM PRATENSE	A, H	
3865	PHLOXINE B	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3866	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3867	PHOENIX DACTYLIFERA	A, E, H	
3868	PHOSPHATIDYL CHOLINE	E	
3869	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%.
3870	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3871	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient.
3872	PHOTINIA SERRULATA	A, H	
3873	PHRAGMITES AUSTRALIS	A, H	
3874	PHYLLANTHUS AMARUS	A, H	
3875	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.

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Item	Ingredient name	Purpose	Specific requirements
			When ascorbic acid is claimed as a component the plant part is restricted to fruit.
3876	PHYLLOSTACHYS NIGRA	A, E, H	
3877	PHYSALIS ALKEKENGI	A, H	
3878	PHYSALIS PUBESCENS	A, H	
3879	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
3880	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%.
3881	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3882	PHYTOMENADIONE	A, E	
3883	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%.
3884	PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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			for use in the eye. The concentration in the medicine must be no more than 0.1%.
3885	PICEA ABIES	A, H	
3886	PICEA MARIANA	A, H	
3887	PICRASMA EXCELSA	A, E, H	
3888	PICRORRHIZA KURROA	A, E, H	
3889	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%.
3890	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%.
3891	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%.
3892	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3893	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.

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Item	Ingredient name	Purpose	Specific requirements
3894	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3895	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3896	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.
3897	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3898	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3899	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.
3900	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%.
3901	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%.
3902	PILOCARPUS PINNATIFOLIUS	A, H	Pilocarpine is a mandatory component of Pilocarpus pinnatifolius. The concentration of

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			pilocarpine in the medicine must be no more than 0.025%.
3903	PIMENTA FRUIT OIL	A, E, H	
3904	PIMENTA LEAF OIL	A, E, H	
3905	PIMENTA OFFICINALIS	A, E, H	
3906	PIMENTA RACEMOSA	A, E, H	<p>When the plant preparation for Pimenta racemosa is an oil and the concentration of this oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL, a restricted flow insert must be fitted on the container.</p> <p>When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL but 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'.
3907	PIMPINELLA ANISUM	A, E, H	When the plant preparation for Pimpinella anisum is an oil or distillate and the concentration of this oil or distillate in the medicine is more than 50%:

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			<p>a) the nominal capacity of the container must be no more than 50 millilitres; and</p> <p>b) a restricted flow insert is must be fitted on the container; and</p> <p>c) the medicine requires the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
3908	PIMPINELLA SAXIFRAGA	A, E, H	
3909	PINE NEEDLE OIL SCOTCH	A, E, H	
3910	PINE NEEDLE OIL TERPENELESS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3911	PINE OIL AROMATIC	A, E, H	
3912	PINE OIL PUMILIO	A, E, H	
3913	PINEAPPLE	E	
3914	PINEAPPLE OILS	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>
3915	PINELLIA TERNATA	A, H	
3916	PINUS CONTORTA	A, E, H	

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Item	Ingredient name	Purpose	Specific requirements
3917	PINUS ELLIOTTII	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5% If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3918	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%.
3919	PINUS MONTICOLA	A, E, H	
3920	PINUS MUGO	A, E, H	
3921	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%.
3922	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%.
3923	PINUS PONDEROSA	A, E, H	
3924	PINUS RADIATA	A, E, H	
3925	PINUS STROBUS	A, E, H	
3926	PINUS SYLVESTRIS	A, E, H	

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3927	PINUS TABULIFORMIS	A, E, H	
3928	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%.
3929	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%.
3930	PIPER CHABA	A, E, H	
3931	PIPER CUBEBA	A, E, H	
3932	PIPER KADSURA	A, E, H	
3933	PIPER LONGUM	A, E, H	
3934	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

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			<p>more than 25 mg of kavalactones (of Piper methysticum) per dose require the following warning statement on the medicine label:</p> <p>- (PIPER) 'Not for prolonged use. If symptoms persist - seek advice from a healthcare practitioner. Not recommended for pregnant or lactating women (or words to that effect). May harm the liver'.</p> <p>The plant part must be root or rhizome.</p> <p>When for oral use, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome.</p> <p>When for topical use on the rectum, vagina or throat, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome.</p> <p>When the container type is tea bag the maximum quantity per tea bag must be no more than 3 grams of dried whole or peeled root or rhizomes.</p>
3935	PIPER NIGRUM	A, E, H	
3936	PIPER SARMENTOSUM	A, E, H	
3937	PIPERIDINE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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3938	PIPERINE	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary formulation. The total flavour proprietary formulation in a medicine must not be more than 5% and the concentration of piperine in the medicine must not be more than 0.15%.
3939	PIPERITONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3940	PIPERONAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3941	PIPERONYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. If used as in a fragrance the total fragrance concentration in

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Item	Ingredient name	Purpose	Specific requirements
			a medicine must be no more than 1%.
3942	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (PIPBUT) 'Contains piperonyl butoxide' (or words to that effect).
3943	PIROCTONE OLAMINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1% in wash-on/wash-off medicines and 0.5% in leave-on medicines.
3944	PISCIDIA PISCIPULA	A, E, H	
3945	PISTACIA LENTISCUS	A, E, H	
3946	PISUM SATIVUM	A, E, H	
3947	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3948	PLANTAGO AFRA	A, E, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. (a) 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:

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Item	Ingredient name	Purpose	Specific requirements
			<p>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</p> <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. <p>(b) When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (PSYLL) 'On medical advice' (or words to that effect).
3949	PLANTAGO ARENARIA	A, H	<p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. <p>(a) 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> <ul style="list-style-type: none"> - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). <p>The requirement specified in paragraph (b) below applies in</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. <p>(b) 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> <ul style="list-style-type: none"> - (PSYLL) 'On medical advice' (or words to that effect).
3950	PLANTAGO ASIATICA	A, H	<p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. <p>(a) 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> <ul style="list-style-type: none"> - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning

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Item	Ingredient name	Purpose	Specific requirements
			<p>statement (PSYLL1) on the label.</p> <p>(b) When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the medicine label:</p> <p>- (PSYLL) 'On medical advice' (or words to that effect).</p>
3951	PLANTAGO LANCEOLATA	A, E, H	<p>The medicine requires the following warning statement on the medicine label:</p> <p>- (CHILD5) 'Use in children under 3 years is not recommended'</p> <p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:</p> <p>- is listed in the Register on or after 2 March 2020; or</p> <p>- is released for supply after 2 March 2021.</p> <p>(a) 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> <p>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</p> <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <p>- is listed in the Register before 2 March 2020; and</p> <p>- is released for supply before 2 March 2021; and</p> <p>- does not have the warning statement (PSYLL1) on the</p>

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Item	Ingredient name	Purpose	Specific requirements
			label. (b) 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: - (PSYLL) 'On medical advice' (or words to that effect).
3952	PLANTAGO MAJOR	A, E, H	<p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. <p>(a) 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> <ul style="list-style-type: none"> - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. <p>(b) 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> <ul style="list-style-type: none"> - (PSYLL) 'On medical advice'

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Item	Ingredient name	Purpose	Specific requirements (or words to that effect).
3953	PLANTAGO OVATA	A, H	<p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. <p>(a) 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> <ul style="list-style-type: none"> - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. <p>(b) When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (PSYLL) 'On medical advice' (or words to that effect).
3954	PLANTAGO SEED DRY	A, H	The requirement specified in paragraph (a) below applies to

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Item	Ingredient name	Purpose	Specific requirements
			<p>a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. <p>(a) 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> <ul style="list-style-type: none"> - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. <p>(b) When a dose for children is stated, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (PSYLL) 'On medical advice' (or words to that effect).
3955	PLATANUS OCCIDENTALIS	A, E, H	
3956	PLATANUS RACEMOSA	A, H	
3957	PLATANUS × HISPANICA	A, H	
3958	PLATYCODON GRANDIFLORUS	A, E, H	
3959	PLECTRANTHUS BARBATUS	A, E, H	
3960	PLICATONE	E	Permitted for use only in combination with other permitted ingredients as a

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Item	Ingredient name	Purpose	Specific requirements
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3961	PLUM	E	
3962	PLUMBAGO EUROPAEA	A, H	
3963	PLUMERIA ALBA	A, E, H	
3964	PLUMERIA RUBRA	A, E, H	
3965	POA NEMORALIS	A, H	
3966	POA PRATENSIS	A, H	
3967	PODOPHYLLUM PELTATUM	A, H	Podophyllin and podophyllotoxin are mandatory components of Podophyllum peltatum. The concentration of podophyllin in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%. The concentration of podophyllotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3968	POGOSTEMON CABLIN	A, E, H	
3969	POLACRILIN	E	
3970	POLACRILIN POTASSIUM	E	
3971	POLAPREZINC	A	Only for use in oral medicines. Zinc is a mandatory component of Polaprezinc. The maximum recommended daily dose must be no more than 34 milligrams of zinc sourced from polaprezinc. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily

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			dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect).
3972	POLIGLUSAM	A, E	The average molecular mass of poliglusam must be greater than 2 kilodaltons. When for internal use, the medicine must not contain more than 1750 milligrams of poliglusam per maximum recommended daily dose. When for internal use, the following warning statements are required on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect); and - (SFOOD) 'Derived from seafood'. When for internal use and the dosage form is a powdered preparation, the medicine requires the following warning statements 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

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Item	Ingredient name	Purpose	Specific requirements
			medicines for dermal application.
3973	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	<p>When for oral use, the medicine must provide no more than 2000 milligrams of Poliglusam derived from <i>Aspergillus niger</i> per maximum recommended daily dose and requires the following warning statement on the medicine label:</p> <p>- (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect).</p> <p>If the medicine is a powdered dosage form, the medicine also requires the following warning statement on the medicine label:</p> <p>- '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>
3974	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</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use. - (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use. - (VITA3) ‘The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’ <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p>
3975	POLLEN	E	<p>The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect).

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Item	Ingredient name	Purpose	Specific requirements
3976	POLOXAMER	E	Only for use in topical medicines for dermal application.
3977	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%.
3978	POLOXAMINE 1301	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3979	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%.
3980	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%.
3981	POLYACRYLATE CROSSPOLYMER-6	E	Only for use in topical medicines for dermal application and not to be

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Item	Ingredient name	Purpose	Specific requirements
			included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3982	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%.
3983	POLYACRYLIC ACID	E	
3984	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3985	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%.
3986	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3987	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%.

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Item	Ingredient name	Purpose	Specific requirements
3988	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%.
3989	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%.
3990	POLYDEXTROSE	E	
3991	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%.
3992	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%
3993	POLYESTER-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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			for use in the eye. The concentration in the medicine must be no more than 1.5%.
3994	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%.
3995	POLYESTER-7	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3996	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%.
3997	POLYETHYLENE	E	
3998	POLYGALA CHINENSIS	A, H	
3999	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.
4000	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
4001	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
4002	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%.
4003	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%.
4004	POLYGLYCERYL-2 DIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3.0%.
4005	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
4006	POLYGLYCERYL-2 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			for use in the eye. The concentration in the medicine must not be more than 3%.
4007	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%.
4008	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
4009	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%.
4010	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4011	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 0.5%.
4012	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%.
4013	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%.
4014	POLYGLYCERYL-3 POLYRICINOLEATE	E	
4015	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIME R DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4016	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%.
4017	POLYGLYCERYL-4	E	Only for use in topical

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
	ISOSTEARATE		medicines for dermal 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%.
4018	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
4019	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%.
4020	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
4021	POLYGONATUM MULTIFLORUM	A, H	
4022	POLYGONATUM OFFICINALE	A, H	
4023	POLYGONATUM SIBIRICUM	A, E, H	
4024	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%.
4025	POLYGONUM BISTORTA	A, H	
4026	POLYGONUM ODORATUM	A, H	

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Item	Ingredient name	Purpose	Specific requirements
4027	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
4028	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.
4029	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
4030	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%.
4031	POLYMETHACRYLIC ACID	E	
4032	POLYMETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
4033	POLYMETHYLSILSESQUIOXAN E	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			for use in the eye. The concentration in the medicine must be no more than 3%.
4034	POLYPORUS UMBELLATUS	A, H	
4035	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
4036	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%.
4037	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
4038	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4039	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
4040	POLYQUATERNIUM-24	E	2%. Only for use in topical medicines for dermal application.
4041	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
4042	POLYQUATERNIUM-37	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4043	POLYQUATERNIUM-4	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 0.4%.
4044	POLYQUATERNIUM-44	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.
4045	POLYQUATERNIUM-51	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 5%.
4046	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
4047	POLYSILICONE-11	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.1%
4048	POLYSILICONE-14	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration of Polysilicone-14 must be no more than 1%.
4049	POLYSILICONE-15	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

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Item	Ingredient name	Purpose	Specific requirements
4050	POLYSILICONE-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.13%.
4051	POLYSORBATE 20	E	
4052	POLYSORBATE 40	E	
4053	POLYSORBATE 60	E	
4054	POLYSORBATE 65	E	
4055	POLYSORBATE 80	E	
4056	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4057	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%.
4058	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.
4059	POLYURETHANE-62	E	Only for use in topical medicines for dermal application and not to be

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4060	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4061	POLYVINYL ACETATE PHTHALATE	E	
4062	POLYVINYL ALCOHOL	E	
4063	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4064	POMEGRANATE	E	
4065	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4066	PONCIRUS TRIFOLIATA	A, H	When used internally, oxedrine is a mandatory component of Poncirus trifoliata. The quantity of Oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4067	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%.
4068	PONTERERIA CRASSIPES	A, H	
4069	POPPY SEED	E, H	
4070	POPPY SEED OIL	E, H	

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Item	Ingredient name	Purpose	Specific requirements
4071	POPULUS ALBA	A, H	
4072	POPULUS BALSAMIIFERA	A, E, H	
4073	POPULUS CANDICANS	A, H	
4074	POPULUS DELTOIDES	A, H	
4075	POPULUS NIGRA	A, H	
4076	POPULUS TREMULA	A, H	
4077	POPULUS TREMULOIDES	A, H	
4078	PORCINE	H	Only for use as an active homoeopathic ingredient.
4079	PORPHYRIDIVM PURPUREUM EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4080	PORTULACA OLERACEA	A, E, H	
4081	POTABLE WATER	E	
4082	POTASSIVM ACETATE	E	
4083	POTASSIVM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4084	POTASSIVM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4085	POTASSIVM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4086	POTASSIVM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.

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Item	Ingredient name	Purpose	Specific requirements
4087	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.
4088	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.
4089	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.
4090	POTASSIUM BICARBONATE	E	
4091	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4092	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

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Item	Ingredient name	Purpose	Specific requirements
			of the preparation must not exceed 11.5.
4093	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4094	POTASSIUM CHLORIDE	A, E, H	<p>When for oral use:</p> <p>a) potassium is a mandatory component of potassium chloride;</p> <p>b) the medicine requires the following warning statement on the medicine label: - (POTAS) 'Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and</p> <p>c) other than when used for oral rehydration therapy, the concentration must be no more than 550 mg per dosage unit.</p> <p>Medicines for use as oral rehydration therapy, are subject to the following conditions:</p> <p>a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts;</p> <p>b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations</p>

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Item	Ingredient name	Purpose	Specific requirements
			Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and c) the medicine requires the warning statements: - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration in the medicine must be no more than 3.75%.
4095	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.
4096	POTASSIUM COCOYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
4097	POTASSIUM COCOYL HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.
4098	POTASSIUM DICHROMATE	H	Only for use as an active homeopathic ingredient.

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Item	Ingredient name	Purpose	Specific requirements
4099	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.
4100	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.
4101	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.
4102	POTASSIUM HYDROXYCITRATE	A, H	
4103	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.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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.
4104	POTASSIUM IODIDE	A, E, H	<p>Iodine is a mandatory component of potassium iodide.</p> <p>The percentage of iodine from potassium iodide should be calculated based on the molecular weight of potassium iodide.</p> <p>When for internal use, the maximum recommended daily dose of the medicine must contain less than 300 micrograms of iodine.</p> <p>When for external use, the concentration of iodine in the medicine (excluding salts derivatives or iodophors) must not exceed 2.5%.</p>
4105	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>
4106	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>

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
4107	POTASSIUM NITRATE	A, H	Only for dental use. The concentration in the medicine must be no more than 5%.
4108	POTASSIUM OROTATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium orotate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4109	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%.
4110	POTASSIUM SORBATE	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4111	POTASSIUM STANNATE	E	Permitted for use only in

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Item	Ingredient name	Purpose	Specific requirements
			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%.
4112	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4113	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.
4114	POTATO STARCH	E	
4115	POTENTILLA ANSERINA	A, H	
4116	POTENTILLA CHINENSIS	A, H	
4117	POTENTILLA DISCOLOR	A, H	
4118	POTENTILLA ERECTA	A, E, H	
4119	POTENTILLA REPTANS	A, H	
4120	POTERIUM OFFICINALE	A, E, H	
4121	POTERIUM SANGUISORBA	A, H	
4122	POVIDONE	E	
4123	POWDERED CELLULOSE	E	
4124	PPG-1-PEG-9 LAURYL GLYCOL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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Item	Ingredient name	Purpose	Specific requirements
			The concentration in the medicine must be no more than 5%.
4125	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%.
4126	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%.
4127	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%.
4128	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%.

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Item	Ingredient name	Purpose	Specific requirements
4129	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4130	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%.
4131	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4132	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%.
4133	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4134	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%.
4135	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.

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Item	Ingredient name	Purpose	Specific requirements
4136	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4137	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4138	PRALINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4139	PREGELATINISED MAIZE STARCH	E	
4140	PREGELATINISED POTATO STARCH	E	
4141	PREGELATINISED RICE STARCH	E	
4142	PREGELATINISED STARCH	E	
4143	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4144	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%.
4145	PRICKLY ASH BARK DRY	A, H	

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Item	Ingredient name	Purpose	Specific requirements
4146	PRICKLY ASH BARK POWDER	A, H	
4147	PRIMULA VERIS	A, E, H	
4148	PRIMULA VULGARIS	A, E, H	
4149	PRINSEPIA UNIFLORA	A, H	
4150	PROBOSCIDEA PARVIFLORA	A, H	
4151	PROGESTERONE	H	Only for use as an active homoeopathic ingredient.
4152	PROLINE	A, E	
4153	PROPAN-1-OL	E	<p>Only for use in:</p> <ul style="list-style-type: none"> - topical medicines for dermal application; or - in combination with other permitted ingredients as a flavour proprietary excipient formulation. <p>The concentration of propan-1-ol in the medicine must not be more than 18%.</p> <p>When used in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation, the total flavour proprietary excipient formulation in a medicine must not be more than 5%.</p>
4154	PROPANE	E	Only for use as an excipient propellant ingredient.
4155	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>
4156	PROPENYL GUAETHOL	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
4157	PROPIONALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a 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>
4158	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>
4159	PROPIONYLLEVOARNITINE HYDROCHLORIDE	A, H	
4160	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</p>

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			<p>following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4161	PROPOLIS BALSAM	A, E	<p>Lead is a mandatory component of Propolis balsam. 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' 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>
4162	PROPOLIS DRY EXTRACT	A, E	<p>Lead is a mandatory component of Propolis dry extract. The concentration of lead in the medicine must be no more</p>

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			<p>than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4163	PROPOLIS LIQUID EXTRACT	A, E	<p>Lead is a mandatory component of Propolis liquid extract.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4164	PROPOLIS RESIN	A, E	Lead is a mandatory

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			<p>component of propolis resin.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4165	PROPOLIS TINCTURE	A, E	<p>Lead is a mandatory component of Propolis tincture.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>

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4166	PROPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4167	PROPYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4168	PROPYL GALLATE	E	
4169	PROPYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4170	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4171	PROPYLENE GLYCOL	E	
4172	PROPYLENE GLYCOL ALGINATE	E	Permitted for use only in combination with other permitted ingredients as a

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			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4173	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%.
4174	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%.
4175	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4176	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4177	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4178	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

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			1%.
4179	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4180	PROPYLENE GLYCOL MONOLAUARATE	E	Only for use in topical medicines for dermal application.
4181	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4182	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4183	PROSOPIS JULIFLORA	A, H	
4184	PROTEASE	A	<p>Must be derived from <i>Aspergillus oryzae</i> or <i>Aspergillus niger</i>.</p> <p>When the dosage form is undivided, the units 'haemoglobin unit on the tyrosine basis per gram' and 'Thousand haemoglobin units on the tyrosine basis per gram' are permitted.</p> <p>When the dosage form is divided, the units 'haemoglobin units on the tyrosine basis' and 'thousand haemoglobin units on the tyrosine basis' are permitted.</p>
4185	PROTEIN HYDROLYSATE	E	
4186	PRUNE JUICE	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%.
4187	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%.
4188	PRUNELLA VULGARIS	A, H	
4189	PRUNUS AFRICANA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus africana. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4190	PRUNUS ARMENIACA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus armeniaca and must be declared in the application. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4191	PRUNUS AVIUM	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus avium. The concentration of

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

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4195	PRUNUS DULCIS	A, E, H	<p>microgram/L or 0.0000001%.</p> <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>
4196	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>
4197	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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4198	PRUNUS LAUROCERASUS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4199	PRUNUS MUME	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus mume.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4200	PRUNUS PERSICA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus persica.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4201	PRUNUS SALICINA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p>

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			The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4202	PRUNUS SEROTINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus serotina. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4203	PRUNUS SPINOSA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4204	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4205	PSEUDOCYDONIA SINENSIS	A, H	
4206	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4207	PSEUDOTSUGA MENZIESII	A, H	
4208	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4209	PSIDIUM GUAJAVA	A, E, H	
4210	PSORALEN (OF CULLEN	E	

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	CORYLIFOLIUM)		
4211	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4212	PSYLLIUM HUSK DRY	A, H	<p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. <p>(a) When a dose for children is stated, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. <p>(b) When a dose for children is stated, the following warning statement is required on medicine label:</p> <ul style="list-style-type: none"> - (PSYLL) 'On medical advice' (or words to that effect).
4213	PSYLLIUM HUSK POWDER	A, E, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:

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			<p>- is listed in the Register on or after 2 March 2020; or</p> <p>- is released for supply after 2 March 2021.</p> <p>(a) 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> <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <p>- is listed in the Register before 2 March 2020; and</p> <p>- is released for supply before 2 March 2021; and</p> <p>- does not have the warning statement (PSYLL1) on the label.</p> <p>(b) When a dose for children is stated, the following warning statement is required on the label:</p> <p>- (PSYLL) 'On medical advice' (or words to that effect).</p>
4214	PSYLLIUM SEED DRY	A, E, H	<p>The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that:</p> <p>- is listed in the Register on or after 2 March 2020; or</p> <p>- is released for supply after 2 March 2021.</p> <p>(a) When a dose for children is stated the following warning statement is required on the label:</p>

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			<p>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).</p> <p>The requirement specified in paragraph (b) below applies in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register before 2 March 2020; and - is released for supply before 2 March 2021; and - does not have the warning statement (PSYLL1) on the label. <p>(b) When a dose for children is stated, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> - (PSYLL) 'On medical advice' (or words to that effect).
4215	PTELEA TRIFOLIATA	A, H	
4216	PTEROCARPUS MARSUPIUM	A, H	
4217	PTEROCARPUS SANTALINUS	A, E, H	
4218	PUERARIA LOBATA	A, E, H	
4219	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4220	PULLULAN	E	
4221	PUMICE	E	
4222	PUMPKIN	E	
4223	PUMPKIN SEED	E, H	
4224	PUMPKIN SEED OIL	E, H	
4225	PUNICA GRANATUM	A, E, H	
4226	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4227	PURIFIED HONEY	A, E	When the route of administration is oral, the medicine requires the

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			<p>following warning statement on the medicine label:</p> <p>- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).</p> <p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4228	PURIFIED SILICEOUS EARTH	E, H	
4229	PURIFIED TALC	E	
4230	PURIFIED WATER	E	
4231	PVM/MA COPOLYMER	E	
4232	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4233	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.

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4234	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4235	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>
4236	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 must provide no more than 200 mg of pyridoxine.</p> <p>If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label:</p> <p>- (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'</p>

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4237	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 must provide no more than 200 mg of pyridoxine.</p> <p>If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement 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>
4238	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 must provide no more than 200 mg of pyridoxine.</p> <p>If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per</p>

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			maximum recommended daily dose the medicine requires the following warning statement 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].'
4239	PYROGLUTAMIC ACID	E	
4240	PYROLA DECORATA	A, H	
4241	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%.
4242	PYRROSIA LINGUA	A, H	
4243	PYRROSIA PETIOLOSA	A, H	
4244	PYRROSIA SHEARERI	A, H	
4245	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

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			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%.
4246	PYRUS PYRIFOLIA	A, H	Beta-arbutin is a mandatory component of Pyrus pyrifolia. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4247	PYRUVIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4248	QUASSIA	E	Permitted for use only in combination with other permitted ingredients as a

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			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4249	QUASSIA AMARA	A, E, H	
4250	QUASSIA WOOD JAMAICAN DRY	A, H	
4251	QUASSIA WOOD JAMAICAN POWDER	A, H	
4252	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4253	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4254	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4255	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.
4256	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%.

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4257	QUERCETIN	A	
4258	QUERCETIN DIHYDRATE	A	
4259	QUERCUS ACUTISSIMA	A, H	
4260	QUERCUS ALBA	A, E, H	
4261	QUERCUS PALUSTRIS	A, H	
4262	QUERCUS ROBUR	A, H	
4263	QUERCUS RUBRA	A, H	
4264	QUERCUS VIRGINIANA	A, H	
4265	QUILLAIA DRY	A, H	
4266	QUILLAIA POWDER	A, E, H	
4267	QUILLAIA SAPONARIA	A, H	
4268	QUINCE	E	
4269	QUININE ARSENITE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of Quinine arsenite. The maximum recommended daily dose must be no more than 50 mg of quinine.
4270	QUININE SULFATE DIHYDRATE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of quinine sulfate dihydrate. The maximum recommended daily dose must be no more than 50 mg of quinine.
4271	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4272	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4273	QUISQUALIS INDICA	A, H	
4274	R-ALPHA LIPOIC ACID	A	
4275	RACEMENTHOL	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
4276	RACEMIC CAMPHOR	E, H	<p>Only for use as an active homoeopathic or excipient ingredient.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <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</p>

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			<p>fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4277	RADISH	E	
4278	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>
4279	RANUNCULUS BULBOSUS	A, H	
4280	RANUNCULUS FICARIA	A, H	
4281	RANUNCULUS TERNATUS	A, H	

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4282	RAPE SEED OIL	A, E, H	Allyl isothiocyanate is a mandatory component of rape seed oil when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
4283	RAPHANUS SATIVUS	A, H	
4284	RASPBERRY	E	
4285	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%.
4286	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%.
4287	RASPBERRY ESSENCE	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%.
4288	RASPBERRY JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4289	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%.
4290	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%.
4291	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%.
4292	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%.
4293	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%.
4294	RED ANT	H	Only for use as an active homoeopathic ingredient.
4295	RED CLOVER FLOWER DRY	A, H	

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4296	RED CLOVER FLOWER POWDER	A, H	
4297	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4298	RED DEER	A	
4299	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4300	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4301	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4302	REHMANNIA GLUTINOSA	A, E, H	
4303	REL-1-((1R,2S)-1,2,3,4,5,6,7,8-OCTAHYDRO-1,2,8,8-TETRAMETHYL-2-NAPHTHALENYL)-1-ETHANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4304	RESORCINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4305	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%.

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4306	RESVERATROL	A	<p>Only permitted for use in medicines that are for oral routes of administration.</p> <p>The maximum recommended daily dose of the medicine must not contain more than 150 milligrams of resveratrol.</p> <p>The following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (RESVER) 'Resveratrol may affect the way some medicines work, including Warfarin. Consult your health professional before taking with other medicines (or words to that effect)'; - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)'; and - (CHILD2) 'Not suitable for children'.
4307	RETINOL	A, E	<p>Vitamin A is a mandatory component of retinol.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (VITA2) 'WARNING: If you

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			<p>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>
4308	RETINOL ACETATE	A, E	<p>Vitamin A is a mandatory component of retinol acetate.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not</p>

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			<p>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>
4309	RETINOL PALMITATE	A, E	<p>Vitamin A is a mandatory component of retinol palmitate. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor</p>

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			<p>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>
4310	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4311	RHAMNOSE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4312	RHAMNUS CATHARTICA	A, H	<p>When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine</p>

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			<p>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

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			recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4313	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> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect).</p> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements</p>

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			<p>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'.
4314	RHATANY ROOT DRY	A, H	
4315	RHATANY ROOT POWDER	A, H	
4316	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

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

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			and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4317	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'; <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</p>

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			<p>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'.
4318	RHEUM RHAPONTICUM	A, E, H	<p>The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rheum rhaponticum.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and

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

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4319	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> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical

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			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	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4321	RHODINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4322	RHODINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.

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4323	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.
4324	RHODODENDRON AUREUM	A, H	
4325	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%.
4326	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4327	RHUBARB	E, H	When the route of administration is oral,

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

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); <p>and</p> <ul style="list-style-type: none"> - (LAX2) 'Prolonged use may cause serious bowel problems'.
4328	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

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Item	Ingredient name	Purpose	Specific requirements
			<p>effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and - (LAX4) 'This product may have laxative effect'. <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4329	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</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>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</p>

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Item	Ingredient name	Purpose	Specific requirements
			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'.
4330	RHUS AROMATICA	A, E, H	
4331	RHUS CHINENSIS	A, H	
4332	RHUS GLABRA	A, E, H	
4333	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4334	RIBES GROSSULARIA	A, E, H	
4335	RIBES NIGRUM	A, E, H	
4336	RIBOFLAVIN	A, E	
4337	RIBOFLAVIN SODIUM PHOSPHATE	A, E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4338	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4339	RIBOFLAVINE	A, E	
4340	RIBOFLAVINE SODIUM PHOSPHATE	A, E	

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4341	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4342	RIBOSE	A	<p>Only for use in oral medicines.</p> <p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4343	RICE	E	
4344	RICE BRAN	E	
4345	RICE BRAN OIL	E	
4346	RICE BRAN WAX	A, E, H	
4347	RICE STARCH	E	
4348	RICE VINEGAR	E	
4349	RICE WINE	E	<p>Ethanol is a mandatory component of Rice wine.</p> <p>When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine</p>

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			label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
4350	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4351	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4352	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.
4353	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4354	ROSA ARVENSIS	A, E, H	
4355	ROSA CANINA	A, E, H	
4356	ROSA CYMOSA	A, E, H	
4357	ROSA EGLANTERIA	A, E, H	
4358	ROSA GALLICA	A, E, H	
4359	ROSA LAEVIGATA	A, E, H	
4360	ROSA MULTIFLORA	A, E, H	
4361	ROSA ROXBURGHII FRUIT EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.002%.

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4362	ROSA RUGOSA	A, E, H	
4363	ROSA VILLOSA	A, E, H	
4364	ROSA X CENTIFOLIA	A, E, H	
4365	ROSA X DAMASCENA	A, E, H	
4366	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%.
4367	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%.
4368	ROSE FRUIT FRESH	A, E, H	
4369	ROSE HIP	E	
4370	ROSE OIL	A, E, H	
4371	ROSE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4372	ROSEMARY OIL	A, E, H	Safrole is a mandatory component of Rosemary oil.

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			<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>
4373	ROSMARINUS OFFICINALIS	A, E, H	<p>Camphor and cineole are mandatory components of Rosmarinus officinalis.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p> <p>When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres.</p> <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>In liquid preparations other</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4374	ROYAL JELLY	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4375	ROYAL JELLY FRESH	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh.</p>

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Item	Ingredient name	Purpose	Specific requirements
			The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4376	ROYAL JELLY LYOPHILISED	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly lyophilised. The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4377	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4378	RUBIA CORDIFOLIA	A, H	
4379	RUBIA TINCTORUM	A, H	
4380	RUBUS CHINGII	A, H	
4381	RUBUS CORCHORIFOLIUS	A, H	
4382	RUBUS COREANUS	A, E, H	
4383	RUBUS FRUTICOSUS	A, E, H	

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4384	RUBUS IDAEUS	A, E, H	
4385	RUBUS OCCIDENTALIS	A, E, H	
4386	RUBUS PARVIFOLIUS	A, H	
4387	RUBUS ROSIFOLIUS	A, H	
4388	RUDBECKIA HIRTA	A, H	
4389	RUE OIL	A, H	
4390	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%.
4391	RUMEX ACETOSA	A, H	
4392	RUMEX ACETOSELLA	A, H	
4393	RUMEX CONGLOMERATUS	A, H	
4394	RUMEX CRISPUS	A, E, H	
4395	RUMEX PULCHER	A, H	
4396	RUMEX SCUTATUS	A, H	
4397	RUSCUS ACULEATUS	A, H	
4398	RUTA GRAVEOLENS	A, E, H	
4399	RUTOSIDE	A, E	
4400	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4401	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.
4402	S-ISOPROPYL 3-METHYLTHIOCROTONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 1%.
4403	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%.
4404	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%.
4405	SACCHARIN	E	When the medicine is for oral use, the following warning statement is required on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect).
4406	SACCHARIN SODIUM	E	The medicine requires the following warning statement on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect). When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The

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Item	Ingredient name	Purpose	Specific requirements
			recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4407	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4408	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4409	SACCHAROMYCES CEREVISIAE POLYSACCHARIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4410	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4411	SACCHARUM OFFICINARUM	A, E, H	
4412	SAFFLOWER OIL	A, E, H	
4413	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4414	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%.
4415	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

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Item	Ingredient name	Purpose	Specific requirements
			than 4%.
4416	SAGE OIL DALMATIAN	A	<p>Thujone is a mandatory component of Sage oil dalmatian.</p> <p>The concentration of thujone in the medicine must be no more than 4%.</p> <p>When the concentration of Sage oil dalmatian in the medicine is more than 10% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert and child resistant closure must be fitted on the container and the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
4417	SAGE OIL SPANISH	A, E, H	
4418	SALICORNIA EUROPAEA EXTRACT	E	<p>Only for use in topical medicines for dermal use and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.002%.</p>
4419	SALICYLALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a</p>

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			medicine must be no more 1%.
4420	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4421	SALIX ALBA	A, E, H	
4422	SALIX DAPHNOIDES	A, H	
4423	SALIX DISCOLOR	A, H	
4424	SALIX FRAGILIS	A, H	
4425	SALIX NIGRA	A, H	
4426	SALIX PURPUREA	A, H	
4427	SALSOLA KALI	A, H	
4428	SALVIA CHINENSIS	A, H	
4429	SALVIA FRUTICOSA	A, H	
4430	SALVIA HISPANICA	A, E, H	
4431	SALVIA LAVANDULAEFOLIA	A, H	
4432	SALVIA MILTIORRHIZA	A, H	
4433	SALVIA OFFICINALIS	A, E, H	Thujone is a mandatory component of Salvia officinalis. The concentration of thujone in the medicine must be no more than 4%.
4434	SALVIA SCLAREA	A, E, H	
4435	SAMBUCUS CANADENSIS	A, H	
4436	SAMBUCUS EBULUS	A, H	
4437	SAMBUCUS NIGRA	A, E, H	
4438	SANDALWOOD OIL EAST INDIAN	A, E, H	
4439	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.

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4440	SANICULA EUROPAEA	A, H	
4441	SANTALUM ALBUM	A, E, H	
4442	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.
4443	SAPINDUS MUKOROSI	A, H	
4444	SAPONARIA OFFICINALIS	A, H	
4445	SAPOSHNIKOVIA DIVARICATA	A, H	
4446	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%.
4447	SARGASSUM FUSIFORME	A, H	Iodine is a mandatory component of Sargassum fusiforme. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
4448	SARGASSUM SILIQUASTRUM	A, H	Iodine is a mandatory component of Sargassum siliquastrum.

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			<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>
4449	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>
4450	SATUREIA HORTENSIS	A, H	
4451	SATUREIA MONTANA	A, H	
4452	SAUROPUS SPATULIFOLIUS	A, H	
4453	SAURURUS CHINENSIS	A, H	
4454	SAUSSUREA COSTUS	A, H	
4455	SAVORY OIL SUMMER	A, H	
4456	SAXIFRAGA GRANULATA	A, E, H	
4457	SAXIFRAGA STOLONIFERA	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 0.0816%.</p>
4458	SCAPHIUM SCAPHIGERUM	A, H	
4459	SCHEFFLERA HEPTAPHYLLA	A, H	
4460	SCHINOPSIS QUEBRACHO-	A, H	

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	COLORADO		
4461	SCHINUS MOLLE	A, H	
4462	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%.
4463	SCHISANDRA CHINENSIS	A, E, H	
4464	SCHIZONEPETA TENUIFOLIA	A, E, H	
4465	SCHOENOCAULON OFFICINALE	A, H	The maximum recommended daily dose must contain no more than the equivalent of 1mg of the dry herbal material.
4466	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%.
4467	SCLAREOLIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4468	SCLERANTHUS ANNUUS	A, H	
4469	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4470	SCOPOLIA CARNIOLICA	A, H	The concentration of

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			equivalent dry Scopolia carniolica in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4471	SCROPHULARIA NINGPOENSIS	A, H	
4472	SCROPHULARIA NODOSA	A, H	
4473	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4474	SCUTELLARIA BAICALENSIS	A, E, H	
4475	SCUTELLARIA BARBATA	A, H	
4476	SCUTELLARIA LATERIFLORA	A, E, H	
4477	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%.
4478	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%.
4479	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%.
4480	SECALE CEREALE	A, H	Gluten is a mandatory component of Secale cereale when the plant part is seed and the route of administration is

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Item	Ingredient name	Purpose	Specific requirements other than topical and mucosal.
4481	SEDUM ACRE	A, H	
4482	SELAGINELLA TAMARISCINA	A, H	
4483	SELENICEREUS GRANDIFLORUS	A, E, H	
4484	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>
4485	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</p>

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Item	Ingredient name	Purpose	Specific requirements
			exceeded.'
4486	SELENOMETHIONINE	A	Selenium is a mandatory component of Selenomethionine for oral and sublingual use. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micograms for adults of selenium from dietary supplements should not be exceeded.'
4487	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4488	SEMECARPUS ANACARDIUM	A, H	When the plant part is other than seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
4489	SEMOLINA	E	
4490	SEMPERVIVUM TECTORUM	A, H	
4491	SENEGA ROOT DRY	A, H	
4492	SENEGA ROOT POWDER	A, H	
4493	SENNA ALEXANDRINA	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna alexandrina. When used in oral medicines, if the maximum recommended daily dose contains more than

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Item	Ingredient name	Purpose	Specific requirements
			<p>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</p>

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			<p>following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4494	SENNA FRUIT ALEXANDRIAN DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>- (LAX1) 'Drink plenty of water' (or words to that effect).</p> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4495	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>

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

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Item	Ingredient name	Purpose	Specific requirements
			<p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4496	SENNA FRUIT TINNEVELLY DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect).</p> <p>When not promoted or marketed as laxative, the medicine requires the</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and - (LAX4) 'This product may have laxative effect'. <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4497	SENNA FRUIT TINNEVELLY POWDER	A, H	<p>When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and

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

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4498	SENNA LEAF DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna leaf dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you 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

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			<p>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> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); <p>and</p> <ul style="list-style-type: none"> - (LAX2) 'Prolonged use may cause serious bowel problems'.
4499	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

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			<p>professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and - (LAX4) 'This product may have laxative effect'. <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); <p>and</p> <ul style="list-style-type: none"> - (LAX2) 'Prolonged use may cause serious bowel problems'.
4500	SENNA OCCIDENTALIS	A, H	Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna occidentalis when the route of administration is oral administration.

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			<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</p>

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			<p>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'.
4501	SENNA TORA	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna tora.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning</p>

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			<p>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'.
4502	SEPIA	H	Only for use as an active homoeopathic ingredient.
4503	SEQUOIA SEMPERVIRENS	A, H	
4504	SEQUOIADENDRON GIGANTEUM	A, H	
4505	SERENOA REPENS	A, H	
4506	SERINE	A, E	
4507	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.

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4508	SESAME OIL	A, E, H	
4509	SESAME SEED	E	
4510	SESAMUM INDICUM	A, E, H	
4511	SETARIA ITALICA	A, H	
4512	SHARK CALCIUM CHONDROITIN SULFATE	A	
4513	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)
4514	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%.
4515	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4516	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%.

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4517	SHARK-LIVER OIL	A, E	<p>Vitamin A and Colecalciferol are mandatory components of Shark-liver oil.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use. - (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use. - (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900

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			micrograms retinol equivalents for men.?’
4518	SHEA BUTTER	E	
4519	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4520	SHELLAC	E	
4521	SHEPHERD'S PURSE HERB DRY	A, H	
4522	SHEPHERD'S PURSE HERB POWDER	A, H	
4523	SHERRY WINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4524	SIGESBECKIA ORIENTALIS	A, E, H	
4525	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%.
4526	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%.
4527	SILICA SILYLATE	E	Only for use in topical medicines for dermal

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4528	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4529	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4530	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).
4531	SILVER	H	Only for use as an active homeopathic ingredient. The concentration in the medicine must be no more than 1%.
4532	SILVER BEET	E, H	
4533	SILVER BOROSILICATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine should be no more than 0.6%. Silver is a mandatory component of Silver borosilicate when the route of administration is topical.

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			The concentration of silver in the medicine must be no more than 1%.
4534	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4535	SILYBUM MARIANUM	A, E, H	
4536	SIMABA CEDRON	A, H	
4537	SIMETHICONE	E	
4538	SIMMONDSIA CHINENSIS	A, E, H	
4539	SINAPIS ALBA	A, H	Allyl isothiocyanate is a mandatory component of Sinapis alba when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
4540	SINAPIS ARVENSIS	A, H	
4541	SINOMENIUM ACUTUM	A, H	
4542	SIPHONESTEGIA CHINENSIS	A, H	
4543	SIRAITIA GROSVENORII	A, E, H	
4544	SISYMBRIUM OFFICINALE	A, H	
4545	SKATOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4546	SKIPJACK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of Shark-liver oil.

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Item	Ingredient name	Purpose	Specific requirements
			<p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use. - (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use. - (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’

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Item	Ingredient name	Purpose	Specific requirements
4547	SLIPPERY ELM BARK DRY	A, H	
4548	SLIPPERY ELM BARK POWDER	A, E, H	
4549	SMILAX ARISTOLOCHIIIFOLIA	A, H	
4550	SMILAX CHINA	A, H	
4551	SMILAX GLABRA	A, H	
4552	SMILAX OFFICINALIS	A, E, H	
4553	SMILAX ORNATA	A, E, H	
4554	SMOKE EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4555	SODIUM ACETATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4556	SODIUM ACETYLATED HYALURONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4557	SODIUM ACID CITRATE	A, E, H	When used as an active ingredient, only for use in oral medicines.

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Item	Ingredient name	Purpose	Specific requirements
			<p>When used as an active, only for use in oral medicines.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’</p>
4558	SODIUM ACRYLATES COPOLYMER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.8%.</p>
4559	SODIUM ACRYLATES CROSSPOLYMER-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 or on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.7 % (w/w).</p>
4560	SODIUM ACRYLOYDIMETHYLTAURATE/VP CROSSPOLYMER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 2% (w/w).</p>

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Item	Ingredient name	Purpose	Specific requirements
4561	SODIUM ALGINATE	E	
4562	SODIUM ASCORBATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4563	SODIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When used in a sunscreen, the concentration in the medicine must be no more than 0.1%. When used in products other than sunscreens, the concentration in the medicine must be no more than 0.5%.
4564	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%.
4565	SODIUM BENZOATE	E	Medicines containing benzoates require the following warning statement on the medicine label: - (TBNZO8) 'Contains benzoates' (or words to this

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			<p>effect) if the medicine contains two or more benzoate sources or ‘Contains [insert the approved name of benzoate used]’ (or words to this effect) if product contains one benzoate source.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’</p>
4566	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p>
4567	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4568	SODIUM BICARBONATE	A, E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p> <p>When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms.</p> <p>Medicines for use as oral rehydration therapy are subject to the following conditions:</p> <p>a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts;</p> <p>b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.'</p> <p>c) the medicine requires the following warning statements on the medicine label:</p> <p>- (UOAD) 'Use only as directed.'</p> <p>- (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek</p>

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			medical advice (or words to that effect).' - (DIAR3) 'If diarrhoea persists, seek medical advice.'
4569	SODIUM BISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4570	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4571	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4572	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4573	SODIUM CARBONATE	E	When for oral or sublingual use and the total amount of sodium

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			from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4574	SODIUM CARBONATE MONOHYDRATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4575	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%.
4576	SODIUM CARRAGEENAN	E	
4577	SODIUM CASEINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4578	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4579	SODIUM CHLORIDE	A, E, H	
4580	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>
4581	SODIUM CITRATE	A, E	<p>Only for oral use when used as an active ingredient.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more</p>

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			than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4582	SODIUM CITRATE DIHYDRATE	A, E	Only for oral use when used as an active ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4583	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%.
4584	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4585	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4586	SODIUM CYCLAMATE	E	When for oral or sublingual use

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			and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).
4587	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4588	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%.
4589	SODIUM DODECYLBENZENESULFONAT E	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4590	SODIUM ERYTHORBATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state

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			quantity and units] of sodium' (or words to that effect).
4591	SODIUM ETHYL HYDROXYBENZOATE	E	
4592	SODIUM FLUORIDE	A, E, H	<p>Fluoride is a mandatory component of Sodium fluoride. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When 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 listable therapeutically active ingredient.</p> <p>b) The concentration of fluoride ion must be no 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> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p>

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Item	Ingredient name	Purpose	Specific requirements
4593	SODIUM FUMARATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4594	SODIUM GLYCEROPHOSPHATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4595	SODIUM HYALURONATE	E	Only for use in topical medicines for dermal application.
4596	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4597	SODIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more

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			<p>than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</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>
4598	SODIUM HYDROXYCITRATE	A	
4599	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>
4600	SODIUM HYDROXYMETHYLGLYCINATE	E	<p>Only for use in topical medicines for dermal application.</p>
4601	SODIUM HYPOCHLORITE	E	<p>Chlorine is a mandatory component of Sodium hypochlorite.</p> <p>The concentration of chlorine in the medicine must be no more than 4%.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning</p>

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Item	Ingredient name	Purpose	Specific requirements
			statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4602	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4603	SODIUM LACTATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4604	SODIUM LAURETH SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4605	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.

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			The concentration in the medicine must be no more than 5%.
4606	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%.
4607	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4608	SODIUM LAURYL PHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4609	SODIUM LAURYL SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium'

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Item	Ingredient name	Purpose	Specific requirements (or words to that effect).
4610	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4611	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4612	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%.
4613	SODIUM METABISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.

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4614	SODIUM METAPHOSPHATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin.</p> <p>The concentration in the medicine must not be more than 0.1%.</p>
4615	SODIUM METHYL COCOYL TAURATE	E	<p>Only for dental use.</p> <p>The concentration in the medicine must be no more than 2%.</p>
4616	SODIUM METHYL HYDROXYBENZOATE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p> <p>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:</p> <p>- (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved name of hydroxybenzoate used]’ (or words to this effect) if product contains one hydroxybenzoate source.</p>

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4617	SODIUM MOLYBDATE DIHYDRATE	A	<p>Only for use in oral medicines.</p> <p>Molybdenum is a mandatory component of Sodium molybdate dihydrate.</p> <p>The percentage of molybdenum from sodium molybdate dihydrate should be calculated based on the molecular weight of sodium molybdate dihydrate.</p> <p>The maximum daily dose of molybdenum from Sodium molybdate dihydrate must be no more than 125 micrograms.</p>
4618	SODIUM MONOFLUOROPHOSPHATE	A	<p>Fluoride is a mandatory component of sodium monofluorophosphate.</p> <p>Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene.</p> <p>When 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 listable therapeutically active ingredient.</p> <p>b) The concentration of fluoride ion must be no 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> <p>When for oral or sublingual use and the total amount of sodium</p>

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			from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4619	SODIUM MYRISTOYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0164%.
4620	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4621	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4622	SODIUM PANTOTHENATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4623	SODIUM PCA	E	Only for use in topical medicines for dermal

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4624	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 for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p> <p>The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 March 2020; or - is released for supply after 2 March 2021. <p>(a) 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

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			<p>taken by children under 12 years old' (or words to that effect); or</p> <p>- (ADULT) 'Adults only' (or words to that effect).</p> <p>(b) When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <p>- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or</p> <p>- (ADULT) 'Adults only' (or words to that effect).</p> <p>(c) 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>(d) 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>
4625	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</p>

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Item	Ingredient name	Purpose	Specific requirements
			15%.
4626	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4627	SODIUM POLYACRYLATE STARCH	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 1%.
4628	SODIUM POLYMETAPHOSPHATE	E	
4629	SODIUM PROPIONATE	E	Only for use in topical medicines for dermal application.
4630	SODIUM PROPYL HYDROXYBENZOATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect). Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved

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			name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4631	SODIUM RNA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
4632	SODIUM SELENATE	A, H	Selenium is a mandatory component of sodium selenate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4633	SODIUM SELENATE DECAHYDRATE	A	Selenium is a mandatory component of sodium selenate decahydrate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label:

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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.'
4634	SODIUM SELENITE	A, H	<p>Selenium is a mandatory component of Sodium selenite. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label:</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>
4635	SODIUM SELENITE PENTAHYDRATE	A	<p>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:</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</p>

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Item	Ingredient name	Purpose	Specific requirements
			supplements should not be exceeded.’
4636	SODIUM SILICATE	E	<p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p>
4637	SODIUM STARCH GLYCOLLATE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p>
4638	SODIUM STARCH GLYCOLLATE TYPE A	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine</p>

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			requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4639	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4640	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%.
4641	SODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4642	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4643	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%.

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4644	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4645	SODIUM SULFATE	A, E, H	<p>When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX4) 'Substance may have a laxative effect'.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</p>
4646	SODIUM SULFATE DECAHYDRATE	A, E, H	<p>When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX4) 'Substance may have a laxative effect'.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</p>

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4647	SODIUM SULFITE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</p> <p>Medicines containing sulfites salts require the following warning statement on the medicine label:</p> <p>- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.</p>
4648	SODIUM SULFITE HEPTAHYDRATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Medicines containing sulfites salts require the following warning statement on the medicine label:</p> <p>- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.</p>
4649	SODIUM TRIPOLYPHOSPHATE	E	<p>Only for use when the route of administration is topical for</p>

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			dermal application, mucous membrane (buccal mucosa) or dental. Not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4650	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.
4651	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.
4652	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%.
4653	SOLANUM MELONGENA	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of

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Item	Ingredient name	Purpose	Specific requirements
			Solanum melongena. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4654	SOLANUM NIGRUM	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum nigrum. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4655	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.
4656	SOLIDAGO GIGANTEA	A, H	
4657	SOLIDAGO GIGANTEA MIS	A, E, H	
4658	SOLIDAGO VIRGAUREA	A, E, H	
4659	SOLUBLE MAIZE STARCH	E	
4660	SOLUBLE POTATO STARCH	E	
4661	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4662	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4663	SOLVENT VIOLET 13	E	Permitted for use only as a

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			colour for topical use.
4664	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%.
4665	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4666	SOPHORA FLAVESCENS	A, E, H	
4667	SOPHORA TONKINENSIS	A, H	
4668	SORBIC ACID	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4669	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4670	SORBITAN MONO-OLEATE	E	
4671	SORBITAN MONOLAURATE	E	
4672	SORBITAN MONOSTEARATE	E	
4673	SORBITAN OLEATE	E	
4674	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%.

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4675	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%.
4676	SORBITAN SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
4677	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4678	SORBITAN STEARATE	E	
4679	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4680	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.
4681	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

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Item	Ingredient name	Purpose	Specific requirements
			<p>British Pharmacopoeia, as in force or existing from time to time.</p> <p>When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).'</p>
4682	SORBITOL SOLUTION (70 PER CENT) (NON-CRYSTALLISING)	A, E	<p>Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (non-crystallising).</p> <p>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.</p> <p>When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a</p>

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Item	Ingredient name	Purpose	Specific requirements
			laxative effect or cause diarrhoea (or words to that effect).'
4683	SORBUS AUCUPARIA	A, H	
4684	SORGHUM	E	
4685	SORGHUM VULGARE	A, H	
4686	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4687	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4688	SOY POLYSACCHARIDE	E	
4689	SOY PROTEIN	E	
4690	SOY STEROL	E	
4691	SOYA BEAN	E	
4692	SOYA BRAN	E	
4693	SOYA OIL	A, E, H	
4694	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%.
4695	SOYBEAN GLYCERIDES	E	Only for use in topical medicines for dermal

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			application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4696	SPARGANIUM STOLONIFERUM	A, H	
4697	SPARTIUM JUNCEUM	A, H	
4698	SPATHOLOBUS SUBERECTUS	A, H	
4699	SPEARMINT OIL	A, E, H	Menthol is a mandatory component of spearmint oil. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according

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			<p>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>
4700	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 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</p>

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			<p>more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. <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> <ul style="list-style-type: none"> - (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
4701	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>
4702	SPIGELIA ANTHELMIA	A, H	
4703	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4704	SPIKE LAVENDER OIL	A, E, H	Camphor is a mandatory

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Item	Ingredient name	Purpose	Specific requirements
			<p>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</p>

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			<p>millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4705	SPINACH	E	
4706	SPINACIA OLERACEA	A, E, H	
4707	SPIRODELA POLYRRHIZA	A, H	
4708	SPIRULINA	E	
4709	SPRAY-DRIED GLUCOSE SYRUP	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>
4710	SPRAY-DRIED LIQUID GLUCOSE	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>
4711	SPRUCE OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p>

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4712	SQUALANE	E	Only for use in topical medicines for dermal application.
4713	SQUALENE	A, E	
4714	SQUID OIL	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'. Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in combination with other ingredients in the medicine and be presented in a therapeutic dosage form for therapeutic use.
4715	SQUILL DRY	A, H	
4716	SQUILL INDIAN DRY	A, H	
4717	SQUILL INDIAN POWDER	A, H	
4718	SQUILL POWDER	A, H	
4719	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.'
4720	ST JOHN'S WORT HERB DRY	A, H	When used for oral ingestion, the medicine requires the following warning statement

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			on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4721	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.'
4722	STACHYS OFFICINALIS	A, E, H	
4723	STACHYS PALUSTRIS	A, H	
4724	STACHYURUS HIMALAICUS	A, H	
4725	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%.
4726	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4727	STAR ANISE OIL	A, E	When the concentration in the medicine is more than 50% and the nominal capacity of the container is equal to or less than 50mL, 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

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			of children' (or words to that effect).
4728	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%.
4729	STARCH SODIUM OCTENYL SUCCINATE	E	
4730	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4731	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4732	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4733	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4734	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4735	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

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			medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4736	STEARETH-10	E	Only for use in topical medicines for dermal application.
4737	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%.
4738	STEARETH-2	E	Only for use in topical medicines for dermal application.
4739	STEARETH-20	E	Only for use in topical medicines for dermal application.
4740	STEARETH-21	E	Only for use in topical medicines for dermal application.
4741	STEARETH-5	E	Only for use in topical medicines for dermal application.
4742	STEARIC ACID	E	
4743	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

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 1%.
4744	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%.
4745	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4746	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4747	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4748	STEARYL ALCOHOL	E	
4749	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.
4750	STEARYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			4.5%. The medicine requires the following warning statements on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect) - (EYE) 'Avoid contact with eyes' (or words to that effect).
4751	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4752	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4753	STEARYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4754	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4755	STELLARIA CHAMAEJASME	A, H	
4756	STELLARIA DICHOTOMA	A, H	
4757	STELLARIA MEDIA	A, E, H	
4758	STEMONA JAPONICA	A, H	
4759	STEMONA SESSILIFOLIA	A, H	
4760	STENOTAPHRUM SECUNDATUM	A, H	
4761	STEPHANIA TETRANDA	A, H	
4762	STERCULIA	A, H	
4763	STERCULIA TRAGACANTHA	A, H	
4764	STERCULIA URENS	A, H	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
4765	STEVIA REBAUDIANA	A, E, H	
4766	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4767	STILLINGIA SYLVATICA	A, H	
4768	STORAX PREPARED	A, E, H	
4769	STRAWBERRY	E	
4770	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%.
4771	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'.
4772	STREPTOCOCCUS THERMOPHILUS	A	
4773	STROBILANTHES CUSIA	A, H	
4774	STRONG AMMONIA SOLUTION	E	Ammonia is a mandatory component of dilute ammonia solution. The concentration of ammonia in the medicine must be no more than 0.5%. When for internal use, the

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			concentration in the medicine must be no more than 0.25%.
4775	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4776	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4777	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4778	STRYCHNOS IGNATII	H	Only for use as an active homoeopathic ingredient. Strychnine (of Strychnos spp.) is a mandatory component of Strychnos ignatii. The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4779	STRYCHNOS NUX-VOMICA	A, H	Strychnine (of Strychnos spp.) is a mandatory component of Strychnos nux-vomica. The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4780	STYPHNOLOBIUM JAPONICUM	A, E, H	
4781	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
4782	STYRAX BENZOIN	A, E, H	
4783	STYRAX OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4784	STYRAX PARALLELONEURUM	A, H	
4785	STYRAX TONKINENSIS	A, H	
4786	STYRENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4787	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4788	STYROLYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4789	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4790	SUCCINIC ACID	E	
4791	SUCRALOSE	E	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
4792	SUCROSE	E	<p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4793	SUCROSE ACETATE ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
4794	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>
4795	SUCROSE COCOATE	E	Only for use in topical

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>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>
4796	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4797	SUCROSE LAURATE	E	<p>When for oral or sublingual use, Sucrose is a mandatory component of Sucrose laurate.</p> <p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4798	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4799	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4800	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> <p>- (EYE) 'Avoid contact with the eyes' (or words to that effect)</p> <p>- (EYE2) 'May be irritant to the</p>

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
4801	SUCROSE STEARATE	E	eyes' (or words to that effect). For use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When for topical use, the concentration in the medicine must be no more than 0.25%. For oral use as a manufacturing aid only. When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit.
4802	SUCROSE TRISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
4803	SUDAN III	E	Permitted for use only as a colour for topical use.
4804	SUGAR CANE WAX ALCOHOLS	A, H	The maximum recommended daily dose must not provide more than 12mg. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
4805	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of Sugarcane.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4806	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4807	SULFATED LOW MOLECULAR WEIGHT FUCANS	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 0.025%.</p>
4808	SULFUR DIOXIDE	E	<p>Medicines containing sulfites salts require the following warning statement on the medicine label:</p> <p>- (SULF) 'Contains sulfites' (or words to this effect) if</p>

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4809	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4810	SULFURIC ACID	E, H	Only for use as an active homoeopathic ingredient or excipient ingredient. The concentration in the medicine must be no more than 0.5%.
4811	SULFURISED 1-METHYL-4-(1-METHYLETHENYL)-CYCLOHEXENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4812	SULISOBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or

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Item	Ingredient name	Purpose	Specific requirements
4813	SULISOBENZONE SODIUM	A	words to this effect). Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4814	SUNFLOWER OIL	A, E, H	
4815	SUNFLOWER SEED	E, H	
4816	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4817	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
4818	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4819	SWEDE	E	
4820	SWEET ORANGE OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			permitted 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%.
4821	SWEET POTATO	E	
4822	SWERTIA CHIRATA	A, H	
4823	SWIETENIA MAHOGANI	A, H	
4824	SYAGRUS ROMANZOFFIANA	A, E, H	
4825	SYMPHYOTRICHUM NOVI-BELGII	A, H	
4826	SYMPHYTUM OFFICINALE	H	When used orally as an active homoeopathic ingredient, the concentration must be a dilution of 12X or more. When used in topical medicines for dermal application, the concentration in the preparation must be no more than 10mg/kg or 10mg/L or 0.001%.
4827	SYMPLOCARPUS FOETIDUS	A, H	
4828	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4829	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.
4830	SYNTHETIC WAX	E	
4831	SYRINGA RETICULATA	A, H	
4832	SYRINGA VULGARIS	A, H	

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Item	Ingredient name	Purpose	Specific requirements
4833	SYZYGIIUM AROMATICUM	A, E, H	<p>When the plant preparation is oil or distillate and the concentration of this oil or distillate in the product is greater than 25%, the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>When the plant preparation is oil or distillate, the concentration of this oil or distillate in the medicine is greater than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>When the plant preparation is oil or distillate, the concentration of oil or distillate in the product is greater than 25% and the nominal capacity of the container is less than 15 millilitres, a restricted flow insert must be fitted on the container.</p> <p>When the plant preparation is oil or distillate and the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of the oil or distillate and the concentration of oil or distillate in the product must not be greater than 25%.</p>

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Item	Ingredient name	Purpose	Specific requirements
4834	SYZYGIUM CUMINI	A, H	
4835	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%.
4836	TABEBUIA SERRATIFOLIA	A, E, H	
4837	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%.
4838	TAGETES MINUTA	A, E, H	
4839	TAGETES OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4840	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4841	TALLOW	E	Only for use in topical medicines for dermal application.
4842	TALLOW GLYCERIDES	E	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
4843	TAMARINDUS INDICA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4844	TAMARIX APHYLLA	A, H	
4845	TAMARIX CHINENSIS	A, H	
4846	TAMARIX GALLICA	A, H	
4847	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.
4848	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4849	TANACETUM PARTHENIUM	A, E, H	
4850	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%.
4851	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%.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4852	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.
4853	TANNIC ACID	E	
4854	TAPIOCA STARCH	E	
4855	TARAXACUM MONGOLICUM	A, E, H	
4856	TARAXACUM OFFICINALE	A, E, H	
4857	TARO	E	
4858	TARRAGON OIL	A, E, H	
4859	TARTARIC ACID	E	
4860	TARTRAZINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4861	TARTRAZINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4862	TASMANNIA LANCEOLATA	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4863	TAURINE	A, E	
4864	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4865	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'.
4866	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4867	TERMINALIA CATAPPA	A, H	
4868	TERMINALIA CHEBULA	A, H	
4869	TERMINALIA FERDINANDIANA	A, E, H	Only for use when the plant part is fruit flesh, fruit flesh dry or the preparation is as an aqueous extract of the fruit flesh. When used as an excipient, the ingredient is only for use in

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye.</p> <p>When used as an excipient, the concentration in the medicine must be no more than 0.3%.</p>
4870	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>
4871	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>
4872	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</p>

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more 1%.
4873	TERPINEOL	E	
4874	TERPINEOL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4875	TERPINOLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4876	TERPINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4877	TERPINYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
4878	TERPINYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4879	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4880	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%.
4881	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%.
4882	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

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Item	Ingredient name	Purpose	Specific requirements
			1%.
4883	TETRACLINIS ARTICULATA	A, E, H	
4884	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%.
4885	TETRADIUM RUTICARPUM	A, H	When for internal use, oxedrine is a mandatory component of Tetradium ruticarpum. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4886	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%.
4887	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%.
4888	TETRAHYDRO PARA- METHYLQUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4889	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%.
4890	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%.
4891	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%.
4892	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%.

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Item	Ingredient name	Purpose	Specific requirements
4893	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%.
4894	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%.
4895	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%.
4896	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4897	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%.

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
4898	TETRAPANAX PAPYRIFER	A, H	
4899	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4900	TETRASODIUM PYROPHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4901	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4902	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4903	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4904	THAPSIA GARGANICA	A, H	
4905	THAUMATIN	E	
4906	THEASPIRANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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Item	Ingredient name	Purpose	Specific requirements
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4907	THEMEDA TRIANDRA	A, H	
4908	THEOBROMA CACAO	A, E, H	<p>Caffeine is a mandatory component of Theobroma cacao.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%.</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>The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 September 2019; or - is released for supply after 2 March 2021. <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> - was listed in the Register before 2 September 2019; and - is released for supply before 2 March 2021; <p>may comply with the requirements in paragraphs (a) to (e) below.</p> <p>a) When for internal use or oral application, the maximum recommended daily dose of the</p>

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			<p>medicine must provide no more than 400mg of total caffeine.</p> <p>b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' <p>e) 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</p>

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			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).
4909	THEOBROMA OIL	A, E, H	
4910	THIAMINE	A, E	
4911	THIAMINE HYDROCHLORIDE	A, E	
4912	THIAMINE NITRATE	A, E	
4913	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%.
4914	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%.
4915	THLASPI ARVENSE	A, E, H	
4916	THREONINE	A, E	
4917	THUJA OCCIDENTALIS	A, H	
4918	THUJA PLICATA	A, E, H	
4919	THYME HERB DRY	A, E, H	
4920	THYME OIL	A, E, H	When the concentration of Thyme oil in the medicine is

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Item	Ingredient name	Purpose	Specific requirements
			more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the warning statement: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4921	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.
4922	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.
4923	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

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Item	Ingredient name	Purpose	Specific requirements
			of children' (or words to that effect).
4924	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4925	THYMUS MASTICHINA	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4926	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).
4927	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

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Item	Ingredient name	Purpose	Specific requirements
			(c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4928	THYMUS VULGARIS MIS	A, E, H	When the plant preparation is an oil or distillate, and the concentration of Thymus vulgaris MIS oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4929	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).

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4930	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4931	TILACTASE	A	Must be derived from <i>Aspergillus oryzae</i> and comply with the relevant USP monograph. When the dosage form is undivided, the units 'acid lactase units per gram' and 'Thousand acid lactase units per gram' are permitted. When the dosage form is divided, the units 'acid lactase units' and 'thousand acid lactase units' are permitted.
4932	TILIA CORDATA	A, E, H	
4933	TILIA PLATYPHYLLOS	A, E, H	
4934	TILIA TOMENTOSA	A, H	
4935	TILIA X VULGARIS	A, E, H	
4936	TILIANTOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4937	TIN	H	Only for use as an active homoeopathic ingredient.
4938	TINOSPORA CORDIFOLIA	A, H	
4939	TINOSPORA SINENSIS	A, H	
4940	TITANIUM DIOXIDE	A, E	For use as an active ingredient only in sunscreens for dermal application. The concentration in

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Item	Ingredient name	Purpose	Specific requirements
			<p>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).
4941	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>
4942	TOCOFERSOLAN	E	<p>Only for oral and topical use.</p> <p>When for oral use, the concentration in the medicine must be no more than 10% w/w.</p> <p>When used in topical medicines for dermal application, it is not to be included in medicines intended for use in the eye.</p> <p>When for topical use, the concentration in the medicine must be no more than 0.1%</p>

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4943	TOCOPHEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4944	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%
4945	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4946	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%.
4947	TOLU BALSAM	A, E, H	
4948	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%.

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4949	TOLYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4950	TOLYLALDEHYDE GLYCERYLACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4951	TOMATO	E	
4952	TONKA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4953	TONKA BEAN EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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4954	TONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4955	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4956	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.
4957	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4958	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4959	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4960	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)

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			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect). Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4961	TRAGACANTH	A, E	
4962	TRAMETES VERSICOLOR	A, H	
4963	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4964	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%.
4965	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.

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

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4971	TRANS-2-HEXENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4972	TRANS-2-HEXENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4973	TRANS-2-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4974	TRANS-2-HEXENYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

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Item	Ingredient name	Purpose	Specific requirements
			5%.
4975	TRANS-2-HYDROXYCINNAMIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4976	TRANS-2-OCTENAL	E	trans-2-Octenal must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing trans-2-octenal must not be more than 1% of the total medicine.
4977	TRANS-2-UNDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4978	TRANS-3-HEXENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4979	TRANS-4-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a

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			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4980	TRANS-8-(1-METHYLETHYL)-1-OXASPIRO(4.5)DECAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4981	TRANS-ETHYL 2-OCTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4982	TRANS-METHYL-2-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4983	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of Treacle. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the

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			<p>medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4984	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>
4985	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.
4986	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.
4987	TREMELLA FUCIFORMIS	A, H	
4988	TRIACETIN	E	
4989	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4990	TRIADICA SEBIFERA	A, H	
4991	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.

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4992	TRIBASIC SODIUM PHOSPHATE	E	<p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p>
4993	TRIBEHENIN	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 6%.</p>
4994	TRIBEHENIN PEG-20 ESTERS	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 6%.</p>
4995	TRIBULUS TERRESTRIS	A, E, H	
4996	TRIBUTYL ACETYLCITRATE	E	Permitted for use only in combination with other permitted ingredients as a

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4997	TRICALCIUM PHOSPHATE	E	
4998	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%.
4999	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%.
5000	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
5001	TRICHLOROMETHYLPHENYL ARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5002	TRICHODERMA VIRIDE	A, E, H	
5003	TRICHOSANTHES KIRILOVII	A, E, H	
5004	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
5005	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%.
5006	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%.
5007	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
5008	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%.
5009	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
5010	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
5011	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%.
5012	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%.
5013	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
5014	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
5015	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
5016	TRIETHYL CITRATE	E	
5017	TRIETHYLENE GLYCOL	E	
5018	TRIFOLIUM PRATENSE	A, E, H	
5019	TRIFOLIUM REPENS	A, H	
5020	TRIGONELLA FOENUM- GRAECUM	A, E, H	
5021	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%.
5022	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
5023	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
5024	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%.
5025	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%.
5026	TRIISOSTEARIN	E	Only for use in topical

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicines for dermal application.
5027	TRILAURIN	E	Only for use in topical medicines for dermal application.
5028	TRILISA ODORATISSIMA	A, H	
5029	TRILLIUM ERECTUM	A, H	
5030	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%.
5031	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%.
5032	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%.
5033	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			1%.
5034	TRIMETHYLBENZENEPROPANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5035	TRIMETHYLHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5036	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5037	TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5038	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5039	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient.
5040	TRIOCTANOIN	E	Only for use in topical medicines for dermal application and not to be

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5041	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%.
5042	TRIOLEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
5043	TRIOSTEUM PERFOLIATUM	A, H	
5044	TRIOXAUNDECANEDIOIC ACID	E	
5045	TRIPAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5046	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			0.002%.
5047	TRIS-BIPHENYL TRIAZINE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used topically, the dosage form must not be spray.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
5048	TRISILOXANE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 40%.</p>
5049	TRISODIUM EDETATE	E	<p>Only for use in topical medicines for dermal application.</p>
5050	TRISODIUM ETHYLENEDIAMINE DISUCCINATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			0.2%.
5051	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%.
5052	TRISTEARIN	E	
5053	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.
5054	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.
5055	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%.
5056	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5057	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements application.
5058	TROLAMINE SALICYLATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 12%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
5059	TROLLIUS CHINENSIS	A, H	
5060	TROMETAMOL	E	
5061	TROMETAMOL HYDROCHLORIDE	E	
5062	TROPAEOLUM MAJUS	A, E, H	
5063	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5064	TROPOLONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
5065	TSUGA CANADENSIS	A, H	
5066	TULIPA EDULIS	A, H	Colchicine is a mandatory component of <i>Tulipa edulis</i> .

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			The concentration of colchicine in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
5067	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5068	TURNERA DIFFUSA	A, E, H	Beta-arbutin is a mandatory component of Turnera diffusa. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5069	TURNIP	E	
5070	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than 25%.
5071	TYPHA ANGUSTIFOLIA	A, H	
5072	TYPHA LATIFOLIA	A, H	
5073	TYPHONIUM GIGANTEUM	A, H	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
5074	TYROSINE	A, E	