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**
3648	P-ALPHA-DIMETHYL STYRENE	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%.
3649	P-ANISIC ACID	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 0.3%.
3650	PADIMATE O	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 8%. 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).

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

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3651	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%.
3652	PAEONIA LACTIFLORA	A, E, H	
3653	PAEONIA OBOVATA	A, H	
3654	PAEONIA SUFFRUTICOSA	A, E, H	
3655	PAEONIA VEITCHII	A, H	
3656	PALIURUS SPINA-CHRISTI	A, H	
3657	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3658	PALM FRUIT OIL	A, E, H	
3659	PALM GLYCERIDES	E	
3660	PALM KERNEL OIL	A, E, H	
3661	PALM TOCOTRIENOLS COMPLEX	A, H	
3662	PALMARIA PALMATA	A, H	
3663	PALMAROSA OIL	A, E, H	
3664	PALMIDROL	A	Only permitted for use in medicines limited to oral routes of administration. The maximum recommended daily dose of the medicine must not provide more than 600 mg of palmidrol. The following warning statements (or words to the same effect) are required on the medicine label: - (ANALG) 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.' - (ADULT) ‘Adults only.’ - (21DAYS) ‘Not to be used for more than 21 consecutive days.’
3665	PALMITIC ACID	E	
3666	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3667	PALMITOYL DIPEPTIDE-7	E	Only for use in topical medicines for dermal application and not to

			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.002%.
3668	PALMITOYL HYDROXYPROPYLTRIMONIUM AMYLOPECTIN/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%
3669	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%.
3670	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%.
3671	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%.
3672	PANAX GINSENG	A, E, H	
3673	PANAX JAPONICUS	A, H	
3674	PANAX NOTOGINSENG	A, H	
3675	PANAX PSEUDOGINSENG	A, H	
3676	PANAX QUINQUEFOLIUS	A, H	
3677	PANICUM MILIACEUM	A, H	
3678	PANTETHINE	E	Only for use in topical medicines for dermal application.
3679	PANTHENOL	A, E	
3680	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.

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3681	PANTOLACTONE	E	
3682	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3683	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%.
3684	PAPAIN	A, E	
3685	PAPER	E	Only for use in topical medicines for dermal application.
3686	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%.
3687	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%.
3688	PARA-CRESYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

3689	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%.
3690	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%.
3691	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%.
3692	PARA-ETHOXYBENZALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3693	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.

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3694	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%.
3695	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%.
3696	PARA-HYDROXYBENZOIC ACID	E	
3697	PARA-MENTHA-8-THIOL-3-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3698	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%.
3699	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%.
3700	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%.
3701	PARA-PROPYL ANISOLE	E	Para-propyl anisole must only be included in medicines when in combination with other permitted ingredients as a fragrance and/or flavour proprietary excipient formulation. The total concentration of fragrance proprietary excipient formulations containing para-propyl anisole must not be more than 1% of the total medicine. The total concentration of flavour proprietary excipient formulations containing para-propyl anisole must not be more than 5% of the total medicine.
3702	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%.
3703	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%.

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3704	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%.
3705	PARA-TOLYL ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3706	PARAMERIA LAEVIGATA	A, H	
3707	PARIETARIA JUDAICA	A, H	
3708	PARIS POLYPHYLLA	A, H	
3709	PARIS QUADRIFOLIA	A, H	
3710	PARSLEY	E, H	
3711	PARSLEY HERB DRY	A, E, H	
3712	PARSLEY HERB OIL	A, E, H	
3713	PARSLEY HERB POWDER	A, E, H	
3714	PARSLEY SEED OIL	A, E, H	
3715	PARTHENOCISSUS TRICUSPIDATA	A, H	
3716	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.
3717	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%.
3718	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%.
3719	PASPALUM NOTATUM	A, H	
3720	PASSIFLORA CAERULEA	A, H	
3721	PASSIFLORA EDULIS	E	
3722	PASSIFLORA HERB DRY	A, H	
3723	PASSIFLORA INCARNATA	A, E, H	
3724	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%.
3725	PATENT BLUE V	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3726	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3727	PATRINIA SCABIOSIFOLIA	A, H	
3728	PATRINIA VILLOSA	A, H	
3729	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. When for internal use or oral application, the maximum

	recommended daily dose of the medicine must provide no more than 400 mg of total caffeine. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional

			before taking with other medicines' (or words to that effect).
3730	PAULLINIA PINNATA	A, H	
3731	PAWPAW	E	
3732	PEA	E	
3733	PEA STARCH	E	
3734	PEACH	E	
3735	PEANUT	E	
3736	PEAR	E	
3737	PECAN	E	
3738	PECTIN	A, E	
3739	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%.
3740	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3741	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3742	PEG-12 DILAURATE	E	
3743	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%.
3744	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3745	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3746	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.

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3747	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3748	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%.
3749	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3750	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3751	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3752	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3753	PEG-25 PABA	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3754	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3755	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.

3756	PEG-35 CASTOR OIL	E	
3757	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3758	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%.
3759	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3760	PEG-40 CASTOR OIL	E	
3761	PEG-40 HYDROGENATED CASTOR OIL	E	
3762	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%.
3763	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3764	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3765	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.

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3766	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3767	PEG-55 PROPYLENE GLYCOL OLEATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.6%.
3768	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3769	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%.
3770	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%.
3771	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3772	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3773	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3774	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3775	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3776	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%.
3777	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%.
3778	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%.
3779	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3780	PEG-8 LAURATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. The levels of possible impurities such as ethylene oxide (and related material) must be kept below the level of detection.
3781	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3782	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3783	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%.
3784	PEG/PPG-14/7 DIMETHYL ETHER	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 7%.
3785	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%.
3786	PELARGONIUM GRAVEOLENS	A, E, H	
3787	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%.
3788	PELTIGERA CANINA	A, H	
3789	PENICILLIUM EXPANSUM	A, H	
3790	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.
3791	PENTAERYTHRITYL TETRA-DI-	E	Only for use in topical medicines

	T-BUTYL HYDROXYHYDROCINNAMATE		for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.018%
3792	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%.
3793	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3794	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%.
3795	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%.
3796	PENTASODIUM ETHYLENEDIAMINE TETRAMETHYLENE PHOSPHONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3797	PENTYLENE GLYCOL	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 5%.
3798	PEPPER BLACK	E, H	
3799	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%.
3800	PEPPER WHITE	E, H	
3801	PEPPERMINT AMERICAN EXT.	E	Menthol is a mandatory component of peppermint american ext. When the medicine is for topical use for dermal application: a) the medicine must not be intended for use in the eye or on damaged skin; b) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; c) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). d) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. e) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:

			– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3802	PEPPERMINT LEAF DRY	A, E, H	Menthol is a mandatory component of peppermint leaf dry. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.

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3803	PEPPERMINT LEAF POWDER	A, E, H	Menthol is a mandatory component of peppermint leaf powder. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3804	PEPPERMINT OIL	A, E, H	Menthol is a mandatory component of peppermint 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 to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3805	PEPPERMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. The total fragrance proprietary excipient formulation in a medicine must be no more 1%.

			Menthol is a mandatory component of peppermint oil terpeneless. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3806	PEPPERMINT OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than

			5%. Menthol is a mandatory component of peppermint oil terpenes and terpenoids. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3807	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3808	PERHYDRO-3,6-DIMETHYL-BENZO [B] FURAN-2-ONE	E	Permitted for use only in combination with other permitted

			ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3809	PERILLA FRUTESCENS	A, E, H	
3810	PERILLALDEHYDE	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%.
3811	PERLITE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3812	PERMETHRIN	E	The total concentration of permethrin in the medicine must not be more than 2%.
3813	PERSEA AMERICANA	A, E, H	
3814	PERSIC OIL	A, E, H	Amygdalin and Hydrocyanic acid are mandatory components of Persic oil. The concentration of amygdalin in the medicine must be no more than 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
3815	PERSICARIA CHINENSIS	A, H	
3816	PERSICARIA TINCTORIA	A, H	

3817	PERSIMMON	E	
3818	PERU BALSAM	A, E, H	
3819	PERU BALSAM OIL	A, E, H	
3820	PETITGRAIN MANDARIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour The final concentration of the oil in the flavour does not exceed 30% If used in a flavour the total flavour concentration in a medicine must be no more than 5%
3821	PETITGRAIN 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%.
3822	PETITGRAIN OIL CITRONNIER	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. When included in a medicine for use on the lips the concentration of petitgrain oil citronnier must be no more than 0.1%. When included in dermal creams for infant use the concentration of petitgrain oil citronnier must be no more than 0.5% The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3823	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

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			milligrams.
3824	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%.
3825	PETROSELINUM CRISPUM	A, E, H	
3826	PEUCEDANUM PRAERUPTORUM	A, E, H	
3827	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).
3828	PHALARIS ARUNDINACEA	A, H	
3829	PHALARIS CANARIENSIS	A, H	
3830	PHASEOLUS COCCINEUS	A, H	
3831	PHASEOLUS VULGARIS	A, H	
3832	PHELLINUS ROBINIAE	A, E, H	
3833	PHELLODENDRON AMURENSE	A, E, H	
3834	PHELLODENDRON CHINENSE	A, H	
3835	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3836	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%.
3837	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%.
3838	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%.
3839	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%.
3840	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%
3841	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%.

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3842	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%.
3843	PHENETHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3844	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%.
3845	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%.
3846	PHENOL	E	Only for use in topical medicines

			for dermal application. The concentration of phenol in the medicine must be no more than 1%.
3847	PHENOXYACETALDEHYDE	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%.
3848	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The concentration of phenoxyethanol in the preparation must not exceed 15%.
3849	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%.
3850	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
3851	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3852	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3853	PHENYLACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3854	PHENYLACETALDEHYDE DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3855	PHENYLACETALDEHYDE GLYCERYLACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3856	PHENYLACETIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3857	PHENYLALANINE	A, E	When the maximum recommended daily dose of the medicine provides more than 500 mg phenylalanine, the following warning statement is required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.
3858	PHENYLBENZIMIDAZOLE SULFONIC ACID	A	Only for use as an active ingredient in sunscreens for dermal application and not to be

			included in medicines intended for use in the eye. The concentration in the medicine must not be more than 4%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3859	PHENYLETHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3860	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%.
3861	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%.
3862	PHENYLETHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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			fragrance concentration in a medicine must be no more than 1%.
3863	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%.
3864	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%.
3865	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%.
3866	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%.
3867	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%.
3868	PHENYLPROPANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.16%.
3869	PHLEUM PRATENSE	A, H	
3870	PHLOXINE B	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3871	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3872	PHOENIX DACTYLIFERA	A, E, H	
3873	PHOSPHATIDYL CHOLINE	E	
3874	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%.
3875	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3876	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient. The total concentration of phosphorus in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.
3877	PHOTINIA SERRULATA	A, H	
3878	PHRAGMITES AUSTRALIS	A, H	
3879	PHYLLANTHUS AMARUS	A, H	
3880	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.

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3881	PHYLLOSTACHYS NIGRA	A, E, H	
3882	PHYSALIS ALKEKENGI	A, H	
3883	PHYSALIS PUBESCENS	A, H	
3884	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
3885	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%.
3886	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3887	PHYTOMENADIONE	A, E	
3888	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%.
3889	PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3890	PICEA ABIES	A, H	
3891	PICEA MARIANA	A, H	
3892	PICRASMA EXCELSA	A, E, H	
3893	PICRORRHIZA KURROA	A, E, H	
3894	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%.
3895	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%.
3896	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%.
3897	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3898	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3899	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3900	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3901	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.
3902	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3903	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3904	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.
3905	PILOCARPUS JABORANDI	A, H	Pilocarpine is a mandatory component of Pilocarpus jaborandi.

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			The concentration of pilocarpine in the medicine must be no more than 0.025%.
3906	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%.
3907	PILOCARPUS PINNATIFOLIUS	A, H	Pilocarpine is a mandatory component of Pilocarpus pinnatifolius. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3908	PIMENTA FRUIT OIL	A, E, H	
3909	PIMENTA LEAF OIL	A, E, H	
3910	PIMENTA OFFICINALIS	A, E, H	
3911	PIMENTA RACEMOSA	A, E, H	When the plant preparation for Pimenta racemosa is an oil and the concentration of this oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL, a restricted flow insert must be fitted on the container. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of

			children' (or word to that effect) - (NTAKEN) 'Not to be taken'.
3912	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%: a) the nominal capacity of the container must be no more than 50 millilitres; and b) a restricted flow insert is must be fitted on the container; and c) the medicine requires the following warning statement on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or words to that effect).
3913	PIMPINELLA SAXIFRAGA	A, E, H	
3914	PINE NEEDLE OIL SCOTCH	A, E, H	
3915	PINE NEEDLE OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3916	PINE OIL AROMATIC	A, E, H	
3917	PINE OIL PUMILIO	A, E, H	
3918	PINEAPPLE	E	
3919	PINEAPPLE OILS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3920	PINELLIA TERNATA	A, H	
3921	PINUS CONTORTA	A, E, H	

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3922	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%.
3923	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%.
3924	PINUS MONTICOLA	A, E, H	
3925	PINUS MUGO	A, E, H	
3926	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%.
3927	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%.
3928	PINUS PONDEROSA	A, E, H	
3929	PINUS RADIATA	A, E, H	
3930	PINUS STROBUS	A, E, H	
3931	PINUS SYLVESTRIS	A, E, H	
3932	PINUS TABULIFORMIS	A, E, H	
3933	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%.

3934	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%.
3935	PIPER CHABA	A, E, H	
3936	PIPER CUBEBA	A, E, H	
3937	PIPER KADSURA	A, E, H	
3938	PIPER LONGUM	A, E, H	
3939	PIPER METHYSTICUM	A, H	Kavalactones (of Piper methysticum) is a mandatory component of Piper methysticum. Only for oral use when the dosage form is 'tablet' or 'capsule'; or when the container type is 'tea bag'. When used in oral medicines, the maximum daily dose of kavalactones (of Piper methysticum) must be no more than 250 mg. If the dosage form is tablet or capsule then the quantity of kavalactones (of Piper methysticum) must be no more than 125 mg per tablet or capsule. Oral medicines containing more than 25 mg of kavalactones (of Piper methysticum) per dose require the following warning statement on the medicine label: - (PIPER) 'Not for prolonged use. If symptoms persist - seek advice from a healthcare practitioner. Not recommended for pregnant or lactating women (or words to that effect). May harm the liver'. The plant part must be root or rhizome. When for oral use, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome. When for topical use on the rectum, vagina or throat, the

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			medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome. 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.
3940	PIPER NIGRUM	A, E, H	
3941	PIPER SARMENTOSUM	A, E, H	
3942	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%.
3943	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%.
3944	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%.
3945	PIPERONYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

			If used as a flavour the total flavour concentration in a medicine must be no more than 5%. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3946	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application.
3947	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.
3948	PISCIDIA PISCIPULA	A, E, H	
3949	PISTACIA LENTISCUS	A, E, H	
3950	PISUM SATIVUM	A, E, H	
3951	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3952	PLANTAGO AFRA	A, E, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3953	PLANTAGO ARENARIA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3954	PLANTAGO ASIATICA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used

			for children on medical advice' (or words to that effect).
3955	PLANTAGO LANCEOLATA	A, E, H	The medicine requires the following warning statement on the medicine label: - (CHILD5) 'Use in children under 3 years is not recommended' When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3956	PLANTAGO MAJOR	A, E, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3957	PLANTAGO OVATA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3958	PLANTAGO SEED DRY	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
3959	PLATANUS OCCIDENTALIS	A, E, H	
3960	PLATANUS RACEMOSA	A, H	
3961	PLATANUS × HISPANICA	A, H	
3962	PLATYCODON GRANDIFLORUS	A, E, H	
3963	PLECTRANTHUS BARBATUS	A, E, H	
3964	PLICATONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3965	PLUM	E	
3966	PLUMBAGO EUROPAEA	A, H	
3967	PLUMERIA ALBA	A, E, H	
3968	PLUMERIA RUBRA	A, E, H	
3969	POA NEMORALIS	A, H	
3970	POA PRATENSIS	A, H	
3971	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%.
3972	POGOSTEMON CABLIN	A, E, H	
3973	POLACRILIN	E	
3974	POLACRILIN POTASSIUM	E	
3975	POLAPREZINC	A	Only for use in oral medicines. Zinc is a mandatory component of Polaprezinc. The maximum recommended daily dose must be no more than 34 milligrams of zinc sourced from polaprezinc. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the 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).
3976	POLIGLUSAM	A, E	The average molecular mass of poliglusam must be greater than 2 kilodaltons. When for internal use: (a) the maximum recommended daily dose of the medicine must not provide more than 1750 milligrams poliglusam; and (b) the following warning statement is 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). When for internal use and the dosage form is a powdered preparation, the following warning statement is required on the medicine label: - (DNTPOW) 'Do not take powder alone. Mix with food or fluid'. When used as an excipient, only for use in topical medicines for dermal application.
3977	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	When for oral use: (a) the maximum recommended daily dose of the medicine must not provide more than 2000 mg of Poliglusam derived from Aspergillus niger; (b) the following warning statement (or words to the same effect) is 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.'; and (c) if the medicine is a powdered dosage form, the following warning statement is also required on the medicine label:

			- (DNTPOW) 'Do not take powder alone. Mix with food or fluid.' When used as an excipient, Poliglusam derived from Aspergillus niger is only permitted for use in topical medicines for dermal application.
3978	POLLACK-LIVER OIL	A, E	Colecalciferol and Vitamin A are mandatory components of Pollack-liver oil. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use. - (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.’ When for internal use, the

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			maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
3979	POLLEN	E	The medicine requires the following warning statement on the medicine label: - (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect).
3980	POLOXAMER	E	Only for use in topical medicines for dermal application.
3981	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%.
3982	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%.
3983	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%.
3984	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%.
3985	POLYACRYLATE CROSSPOLYMER-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

			for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3986	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%.
3987	POLYACRYLIC ACID	E	
3988	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3989	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%.
3990	POLYBUTADIENE	E	Only for use as part of an adhesive in topical medicines for dermal application.
3991	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3992	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%.
3993	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%.
3994	POLYDECENE	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3995	POLYDEXTROSE	E	
3996	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%.
3997	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%
3998	POLYESTER-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3999	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%.
4000	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%.
4001	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%.
4002	POLYETHYLENE	E	
4003	POLYGALA CHINENSIS	A, H	
4004	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.
4005	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
4006	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
4007	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%.
4008	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%.
4009	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%.
4010	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
4011	POLYGLYCERYL-2 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

			for use in the eye. The concentration in the medicine must not be more than 3%.
4012	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%.
4013	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
4014	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%.
4015	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4016	POLYGLYCERYL-3 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4017	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%.
4018	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%.
4019	POLYGLYCERYL-3 POLYRICINOLEATE	E	
4020	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIMER DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4021	POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/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%.
4022	POLYGLYCERYL-4 ISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4023	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
4024	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%.
4025	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
4026	POLYGONATUM MULTIFLORUM	A, H	
4027	POLYGONATUM OFFICINALE	A, H	
4028	POLYGONATUM SIBIRICUM	A, E, H	
4029	POLYGONUM AVICULARE	A, E, H	When used as an excipient, the medicine is only for use in topical medicines for dermal application

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			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%.
4030	POLYGONUM BISTORTA	A, H	
4031	POLYGONUM ODORATUM	A, H	
4032	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
4033	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.
4034	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
4035	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%.
4036	POLYMETHACRYLIC ACID	E	
4037	POLYMETHYL METHACRYLATE	E	Methyl methacrylate is a mandatory component of polymethyl methacrylate. Only for use in topical medicines for dermal application. The total concentration of methyl methacrylate as residual monomer in the medicine must not be more than 1%.

4038	POLYMETHYLSILSESQUIOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4039	POLYPORUS UMBELLATUS	A, H	
4040	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
4041	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%.
4042	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
4043	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4044	POLYQUATERNIUM-22	E	Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
4045	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
4046	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
4047	POLYQUATERNIUM-37	E	Only for use in topical medicines

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			for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4048	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%.
4049	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%.
4050	POLYQUATERNIUM-51	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4051	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
4052	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%
4053	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%.
4054	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).
4055	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%.
4056	POLYSORBATE 20	E	
4057	POLYSORBATE 40	E	
4058	POLYSORBATE 60	E	
4059	POLYSORBATE 65	E	
4060	POLYSORBATE 80	E	
4061	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4062	POLYSTYRENE	E	Only for use as part of an adhesive in topical medicines for dermal application.
4063	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%.
4064	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.
4065	POLYURETHANE-62	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4066	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4067	POLYVINYL ACETATE PHTHALATE	E	
4068	POLYVINYL ALCOHOL	E	
4069	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4070	POMEGRANATE	E	
4071	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4072	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.
4073	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%.
4074	PONTEDERIA CRASSIPES	A, H	
4075	POPPY SEED	E, H	
4076	POPPY SEED OIL	E, H	
4077	POPULUS ALBA	A, H	
4078	POPULUS BALSAMIIFERA	A, E, H	
4079	POPULUS CANDICANS	A, H	
4080	POPULUS DELTOIDES	A, H	

4081	POPULUS NIGRA	A, H	
4082	POPULUS TREMULA	A, H	
4083	POPULUS TREMULOIDES	A, H	
4084	PORCINE	H	Only for use as an active homoeopathic ingredient.
4085	PORPHYRIDIUM PURPUREUM EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4086	PORTULACA OLERACEA	A, E, H	
4087	POTABLE WATER	E	
4088	POTASSIUM ACETATE	E	
4089	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4090	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4091	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4092	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4093	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.
4094	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

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			weight of potassium aspartate dihydrate.
4095	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.
4096	POTASSIUM BICARBONATE	E	
4097	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient. The total concentration of potassium bromide in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4098	POTASSIUM CARBONATE	E, H	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4099	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4100	POTASSIUM CHLORIDE	A, E, H	When for oral use: (a) potassium is a mandatory component of potassium chloride; (b) the medicine requires the following warning statement on the medicine label: - (POTAS1) 'If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and (c) except when the medicine is for use as oral rehydration therapy, the amount of potassium

			chloride per dosage unit must not be more than 550 mg. Medicines containing potassium chloride for use as oral rehydration therapy, are subject to the following conditions: (a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; (b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and (c) the following warning statements are required on the medicine label: - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration of potassium chloride in the medicine must not be more than 3.75%.
4101	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.
4102	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%.
4103	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%.
4104	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4105	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.
4106	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.
4107	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.
4108	POTASSIUM HYDROXYCITRATE	A, H	
4109	POTASSIUM IODATE	A, H	Iodine is a mandatory component of potassium iodate. The percentage of iodine from potassium iodate should be calculated based on the molecular weight of potassium iodate. When for use in adults, the medicine must contain a daily dose of no more than 505 micrograms of potassium iodate. When for use in children aged 1-3 years, the medicine must contain a daily dose of no more than 337 micrograms of potassium iodate.

4110	POTASSIUM IODIDE	A, E, H	Iodine is a mandatory component of potassium iodide. The percentage of iodine from potassium iodide should be calculated based on the molecular weight of potassium iodide. When for internal use, the maximum recommended daily dose of the medicine must contains less than 300 micrograms of iodine. When for external use, the concentration of iodine in the medicine (excluding salts derivatives or iodophors) must not exceed 2.5%.
4111	POTASSIUM METABISULFITE	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%.
4112	POTASSIUM METAPHOSPHATE	E	Only for use in topical medicines for dermal 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%.
4113	POTASSIUM NITRATE	A, H	Only for dental use. The concentration in the medicine must be no more than 5%.
4114	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.

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4115	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%.
4116	POTASSIUM SORBATE	E	
4117	POTASSIUM STANNATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4118	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4119	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.
4120	POTATO STARCH	E	
4121	POTENTILLA ANSERINA	A, H	
4122	POTENTILLA CHINENSIS	A, H	
4123	POTENTILLA DISCOLOR	A, H	
4124	POTENTILLA ERECTA	A, E, H	
4125	POTENTILLA REPTANS	A, H	
4126	POTERIUM OFFICINALE	A, E, H	
4127	POTERIUM SANGUISORBA	A, H	
4128	POVIDONE	E	
4129	POWDERED CELLULOSE	E	
4130	PPG-1-PEG-9 LAURYL GLYCOL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

			The concentration in the medicine must be no more than 5%.
4131	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%.
4132	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%.
4133	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%.
4134	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%.
4135	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4136	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%.
4137	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.

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4138	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%.
4139	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4140	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%.
4141	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4142	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4143	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4144	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%.
4145	PREGELATINISED MAIZE STARCH	E	
4146	PREGELATINISED POTATO STARCH	E	
4147	PREGELATINISED RICE STARCH	E	
4148	PREGELATINISED STARCH	E	
4149	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4150	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%.
4151	PRICKLY ASH BARK DRY	A, H	
4152	PRICKLY ASH BARK POWDER	A, H	
4153	PRIMULA VERIS	A, E, H	
4154	PRIMULA VULGARIS	A, E, H	
4155	PRINSEPIA UNIFLORA	A, H	
4156	PROBOSCIDEA PARVIFLORA	A, H	
4157	PROGESTERONE	H	Only for use as an active homoeopathic ingredient. The total concentration of progesterone in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.
4158	PROLINE	A, E	
4159	PROPAN-1-OL	E	Only for use in: - topical medicines for dermal application; or - in combination with other permitted ingredients as a flavour proprietary excipient formulation. The concentration of propan-1-ol in the medicine must not be more than 18%. When used in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation, the total flavour proprietary excipient formulation in a medicine must not be more than 5%.
4160	PROPANE	E	Only for use as an excipient propellant ingredient.
4161	PROPANEDIOL	E	Only for use in topical medicines

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			for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%.
4162	PROPENYL GUAETHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4163	PROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4164	PROPIONIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4165	PROPIONYLLEVOCARNITINE HYDROCHLORIDE	A, H	
4166	PROPOLIS	A, E	Lead is a mandatory component of Propolis. The concentration of lead in the medicine must be no more than

			0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4167	PROPOLIS BALSAM	A, E	Lead is a mandatory component of Propolis balsam. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4168	PROPOLIS DRY EXTRACT	A, E	Lead is a mandatory component of Propolis dry extract. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the

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			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.'
4169	PROPOLIS LIQUID EXTRACT	A, E	Lead is a mandatory component of Propolis liquid extract. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4170	PROPOLIS RESIN	A, E	Lead is a mandatory component of propolis resin. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4171	PROPOLIS TINCTURE	A, E	Lead is a mandatory component of Propolis tincture.

			The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4172	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%.
4173	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%.
4174	PROPYL GALLATE	E	
4175	PROPYL HYDROXYBENZOATE	E	
4176	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4177	PROPYLENE GLYCOL	E	
4178	PROPYLENE GLYCOL ALGINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			medicine must be no more than 5%.
4179	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%.
4180	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%.
4181	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4182	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4183	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4184	PROPYLENE GLYCOL ISOCETETH-3 ACETATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4185	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4186	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4187	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4188	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4189	PROSOPIS JULIFLORA	A, H	

4190	PROTEASE	A	Must be derived from Aspergillus oryzae or Aspergillus niger.
4191	PROTEIN HYDROLYSATE	E	
4192	PRUNE JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4193	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%.
4194	PRUNELLA VULGARIS	A, H	
4195	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%.
4196	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%.
4197	PRUNUS AVIUM	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus avium. The concentration of Amygdalin in the medicine must be 0%.

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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%.
4198	PRUNUS CERASIFERA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera. 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%.
4199	PRUNUS CERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasus. 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%.
4200	PRUNUS DOMESTICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica. 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%.
4201	PRUNUS DULCIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus dulcis when the plant part is seed. When the plant part is seed, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry seed. 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%.

4202	PRUNUS HUMILIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus humilis. 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 JAPONICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus japonica. 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	PRUNUS LAUROCERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus. 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%.
4205	PRUNUS MUME	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus mume. 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%.
4206	PRUNUS PERSICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus persica. 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%.
4207	PRUNUS SALICINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina. 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%.
4208	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%.
4209	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%.
4210	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4211	PSEUDOCYDONIA SINENSIS	A, H	
4212	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4213	PSEUDOTSUGA MENZIESII	A, H	
4214	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4215	PSIDIUM GUAJAVA	A, E, H	
4216	PSORINUM	H	Only for use as an active homoeopathic ingredient.

4217	PSYLLIUM HUSK DRY	A, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4218	PSYLLIUM HUSK POWDER	A, E, H	When a dose for children is stated, the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4219	PSYLLIUM SEED DRY	A, E, H	When a dose for children is stated the following warning statement is required on the label: - (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect).
4220	PTELEA TRIFOLIATA	A, H	
4221	PTEROCARPUS MARSUPIUM	A, H	
4222	PTEROCARPUS SANTALINUS	A, E, H	
4223	PUERARIA LOBATA	A, E, H	
4224	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4225	PULLULAN	E	
4226	PUMICE	E	
4227	PUMPKIN	E	
4228	PUMPKIN SEED	E, H	
4229	PUMPKIN SEED OIL	E, H	
4230	PUNICA GRANATUM	A, E, H	
4231	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4232	PURIFIED HONEY	A, E	When the route of administration is oral, the following warning statement is required on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).
4233	PURIFIED SILICEOUS EARTH	E, H	
4234	PURIFIED TALC	E	

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4235	PURIFIED WATER	E	
4236	PVM/MA COPOLYMER	E	
4237	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4238	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4239	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4240	PYRETHRINS	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%. The medicine requires the following warning statement on the medicine label: - (PYRTH3) 'Contains pyrethrins [insert quantity]' (or words to that effect).
4241	PYRIDOXAL 5-PHOSPHATE	A, E	Pyridoxine is a mandatory component of pyridoxal 5-phosphate. The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate. The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older.

			If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (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].
4242	PYRIDOXAL 5-PHOSPHATE MONOHYDRATE	A	Pyridoxine is a mandatory component of pyridoxal 5-phosphate monohydrate. The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate. The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (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].'
4243	PYRIDOXINE HYDROCHLORIDE	A, E, H	When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of pyridoxine hydrochloride. The percentage of pyridoxine from pyridoxine hydrochloride should be calculated based on the molecular weight of pyridoxine hydrochloride. The maximum recommended daily dose of the medicine must not provide more than: (i) 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive); (ii) 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive); (iii) 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive); (iv) 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive); and (v) 100 mg of pyridoxine for individuals aged 19 years and older. If the maximum recommended daily dose of the medicine provides more than 10 mg of pyridoxine, the following warning statement is required on the medicine label: - (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].'
4244	PYROGLUTAMIC ACID	E	
4245	PYROLA DECORATA	A, H	
4246	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%.
4247	PYRROSIA LINGUA	A, H	
4248	PYRROSIA PETIOLOSA	A, H	
4249	PYRROSIA SHEARERI	A, H	
4250	PYRUS COMMUNIS	A, E, H	Beta-arbutin is a mandatory component of Pyrus communis. 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%.
4251	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

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			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%.
4252	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%.
4253	QUASSIA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4254	QUASSIA AMARA	A, E, H	
4255	QUASSIA WOOD JAMAICAN DRY	A, H	
4256	QUASSIA WOOD JAMAICAN POWDER	A, H	
4257	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4258	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4259	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4260	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.
4261	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%.
4262	QUERCETIN	A	
4263	QUERCETIN DIHYDRATE	A	
4264	QUERCUS ACUTISSIMA	A, H	
4265	QUERCUS ALBA	A, E, H	
4266	QUERCUS PALUSTRIS	A, H	
4267	QUERCUS ROBUR	A, H	
4268	QUERCUS RUBRA	A, H	
4269	QUERCUS VIRGINIANA	A, H	
4270	QUILLAIA DRY	A, H	
4271	QUILLAIA POWDER	A, E, H	
4272	QUILLAJA SAPONARIA	A, H	
4273	QUINCE	E	
4274	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.
4275	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.
4276	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4277	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4278	QUISQUALIS INDICA	A, H	

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4279	R-ALPHA LIPOIC ACID	A	
4280	RACEMENTHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4281	RACEMIC CAMPHOR	E, H	Only for use as an active homoeopathic or excipient ingredient. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect);

			and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
4282	RADISH	E	
4283	RAISIN JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4284	RANUNCULUS BULBOSUS	A, H	
4285	RANUNCULUS FICARIA	A, H	
4286	RANUNCULUS TERNATUS	A, H	
4287	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%.
4288	RAPHANUS SATIVUS	A, H	
4289	RASPBERRY	E	
4290	RASPBERRY BRANDY	E	Permitted for use only in

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			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%.
4291	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%.
4292	RASPBERRY FRUIT EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4293	RASPBERRY JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4294	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%.
4295	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%.
4296	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%.
4297	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%.
4298	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%.
4299	RED ANT	H	Only for use as an active homoeopathic ingredient.
4300	RED CLOVER FLOWER DRY	A, H	
4301	RED CLOVER FLOWER POWDER	A, H	
4302	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4303	RED DEER	A	
4304	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4305	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4306	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4307	REHMANNIA GLUTINOSA	A, E, H	
4308	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%.
4309	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%.

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4310	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%.
4311	RESVERATROL	A	Only permitted for use in medicines that are for oral routes of administration. The maximum recommended daily dose of the medicine must not contain more than 150 milligrams of resveratrol. The following warning statements are required on the medicine label: - (RESVER) 'Resveratrol may affect the way some medicines work, including Warfarin. Consult your health professional before taking with other medicines (or words to that effect).'; - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)'; and - (CHILD2) 'Not suitable for children'.
4312	RETINOL	A, E	Vitamin A is a mandatory component of retinol. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are

			pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (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.'
4313	RETINOL ACETATE	A, E	Vitamin A is a mandatory component of retinol acetate. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (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.'
4314	RETINOL PALMITATE	A, E	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: - (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.’
4315	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4316	RHAMNOSE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4317	RHAMNUS CATHARTICA	A, H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

			- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4318	RHAMNUS FRANGULA	A, H	Glucofrangulins calculated as glucofrangulin A is a mandatory component of Rhamnus frangula. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed

			as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4319	RHATANY ROOT DRY	A, H	
4320	RHATANY ROOT POWDER	A, H	
4321	RHEUM OFFICINALE	A, E, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum officinale. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare

			professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or 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'.
4322	RHEUM PALMATUM	A, E, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum palmatum. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children under 12 years is not recommended’; - (LAX2) ‘Prolonged use may cause serious bowel problems’;

			and - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) ‘Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) ‘This product contains [name of the herb(s) or the chemical component(s)]’; and - (LAX4) ‘This product may have laxative effect’. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children under 12 years is not recommended’; - (LAX1) ‘Drink plenty of water' (or words to that effect); and - (LAX2) ‘Prolonged use may cause serious bowel problems’.
4323	RHEUM RHAPONTICUM	A, E, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rheum rhaponticum. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the

			medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (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'.
4324	RHEUM TANGUTICUM	A, H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a

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

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			cause serious bowel problems'.
4325	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4326	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%.
4327	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%.
4328	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.
4329	RHODODENDRON AUREUM	A, H	
4330	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%.
4331	RHODODENDRON GROENLANDICUM	A, H	
4332	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4333	RHUBARB	E, H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhubarb. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires

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			the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4334	RHUBARB ROOT DRY	A, H	When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of rhubarb root dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on

			the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (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'.
4335	RHUBARB ROOT POWDER	A, H	When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of rhubarb root powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare

			professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4336	RHUS AROMATICA	A, E, H	
4337	RHUS CHINENSIS	A, H	
4338	RHUS GLABRA	A, E, H	
4339	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4340	RIBES GROSSULARIA	A, E, H	
4341	RIBES NIGRUM	A, E, H	
4342	RIBOFLAVIN	A, E	
4343	RIBOFLAVIN SODIUM PHOSPHATE	A, E	
4344	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4345	RIBOFLAVINE	A, E	

4346	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4347	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4348	RIBOSE	A	Only for use in oral medicines.
4349	RICE	E	
4350	RICE BRAN	E	
4351	RICE BRAN OIL	E	
4352	RICE BRAN WAX	A, E, H	
4353	RICE STARCH	E	
4354	RICE VINEGAR	E	
4355	RICE WINE	E	Ethanol is a mandatory component of rice wine.
4356	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4357	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4358	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.
4359	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4360	ROSA ARVENSIS	A, E, H	
4361	ROSA CANINA	A, E, H	
4362	ROSA CYMOSA	A, E, H	
4363	ROSA EGLANTERIA	A, E, H	
4364	ROSA GALLICA	A, E, H	
4365	ROSA LAEVIGATA	A, E, H	
4366	ROSA MULTIFLORA	A, E, H	
4367	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%.
4368	ROSA RUGOSA	A, E, H	
4369	ROSA VILLOSA	A, E, H	
4370	ROSA X CENTIFOLIA	A, E, H	
4371	ROSA X DAMASCENA	A, E, H	
4372	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%.
4373	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%.
4374	ROSE FRUIT FRESH	A, E, H	
4375	ROSE HIP	E	
4376	ROSE OIL	A, E, H	
4377	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%.
4378	ROSEMARY OIL	A, E, H	Safrole is a mandatory component of Rosemary oil. When for internal use then the concentration of safrole in the medicine must be no more than

			0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
4379	ROSMARINUS OFFICINALIS	A, E, H	Camphor and cineole are mandatory components of Rosmarinus officinalis. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. 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. 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: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of

			children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
4380	ROYAL JELLY	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly. 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'.
4381	ROYAL JELLY FRESH	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh. 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'.
4382	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'.
4383	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4384	RUBIA CORDIFOLIA	A, H	
4385	RUBIA TINCTORUM	A, H	
4386	RUBUS CHINGII	A, H	
4387	RUBUS CORCHORIFOLIUS	A, H	
4388	RUBUS COREANUS	A, E, H	
4389	RUBUS FRUTICOSUS	A, E, H	
4390	RUBUS IDAEUS	A, E, H	
4391	RUBUS OCCIDENTALIS	A, E, H	
4392	RUBUS PARVIFOLIUS	A, H	
4393	RUBUS ROSIFOLIUS	A, H	
4394	RUDBECKIA HIRTA	A, H	
4395	RUE OIL	A, H	
4396	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%.
4397	RUMEX ACETOSA	A, H	
4398	RUMEX ACETOSELLA	A, H	
4399	RUMEX CONGLOMERATUS	A, H	
4400	RUMEX CRISPUS	A, E, H	
4401	RUMEX PULCHER	A, H	
4402	RUMEX SCUTATUS	A, H	
4403	RUSCUS ACULEATUS	A, H	
4404	RUTA GRAVEOLENS	A, E, H	
4405	RUTOSIDE	A, E	
4406	RYE	E	Gluten is a mandatory component of Rye when the route of

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			administration is other than topical and mucosal.
4407	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.
4408	S-ISOPROPYL 3-METHYLTHIOCROTONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4409	SABINENE	E	Sabinene must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing sabinene must not be more than 5% of the total medicine.
4410	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%.
4411	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%.
4412	SACCHARIN	E	
4413	SACCHARIN SODIUM	E	
4414	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.

4415	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4416	SACCHAROMYCES CERVISIAE 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%.
4417	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4418	SACCHARUM OFFICINARUM	A, E, H	
4419	SAFFLOWER OIL	A, E, H	
4420	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4421	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%.
4422	SAGE LEAF POWDER	A, H	Thujone is a mandatory component of Sage leaf powder. The concentration of thujone in the medicine must be no more than 4%.
4423	SAGE OIL DALMATIAN	A	Thujone is a mandatory component of Sage oil dalmatian. The concentration of thujone in the medicine must be no more than 4%. When the concentration of Sage oil dalmatian in the medicine is more than 10% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert and child resistant closure must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or word to that effect) - (NTAKEN) ‘Not to be taken’

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4424	SAGE OIL SPANISH	A, E, H	
4425	SALICORNIA EUROPAEA EXTRACT	E	Only for use in topical medicines for dermal use and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
4426	SALICYLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4427	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4428	SALIX ALBA	A, E, H	
4429	SALIX DAPHNOIDES	A, H	
4430	SALIX DISCOLOR	A, H	
4431	SALIX FRAGILIS	A, H	
4432	SALIX NIGRA	A, H	
4433	SALIX PURPUREA	A, H	
4434	SALSOLA KALI	A, H	
4435	SALVIA CHINENSIS	A, H	
4436	SALVIA FRUTICOSA	A, H	
4437	SALVIA HISPANICA	A, E, H	
4438	SALVIA LAVANDULAEFOLIA	A, H	
4439	SALVIA MILTIORRHIZA	A, H	
4440	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%.
4441	SALVIA SCLAREA	A, E, H	

4442	SAMBUCUS CANADENSIS	A, H	
4443	SAMBUCUS EBULUS	A, H	
4444	SAMBUCUS NIGRA	A, E, H	
4445	SANDALWOOD OIL EAST INDIAN	A, E, H	
4446	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4447	SANICULA EUROPAEA	A, H	
4448	SANTALUM ALBUM	A, E, H	
4449	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.
4450	SAPINDUS MUKOROSSI	A, H	
4451	SAPONARIA OFFICINALIS	A, H	
4452	SAPOSHNIKOVIA DIVARICATA	A, H	
4453	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%.
4454	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.
4455	SARGASSUM SILIQUASTRUM	A, H	Iodine is a mandatory component of Sargassum siliquastrum. Only for external use when the concentration of iodine in the medicine (excluding salts

			derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
4456	SASSAFRAS ALBIDUM	A, H	Safrole is a mandatory component of Sassafras albidum. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
4457	SATUREIA HORTENSIS	A, H	
4458	SATUREIA MONTANA	A, H	
4459	SAUROPUS SPATULIFOLIUS	A, H	
4460	SAURURUS CHINENSIS	A, H	
4461	SAUSSUREA COSTUS	A, H	
4462	SAVORY OIL SUMMER	A, H	
4463	SAXIFRAGA GRANULATA	A, E, H	
4464	SAXIFRAGA STOLONIFERA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 0.0816%.
4465	SCAPHIUM SCAPHIGERUM	A, H	
4466	SCHEFFLERA HEPTAPHYLLA	A, H	
4467	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4468	SCHINUS MOLLE	A, H	
4469	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%.
4470	SCHISANDRA CHINENSIS	A, E, H	

4471	SCHIZONEPETA TENUIFOLIA	A, E, H	
4472	SCHOENOCAULON OFFICINALE	A, H	The maximum recommended daily dose of the medicine must not contain more than the equivalent of 1 mg of the dry herbal material. The concentration of total alkaloids of Schoenocaulon officinale in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4473	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%.
4474	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%.
4475	SCLERANTHUS ANNUUS	A, H	
4476	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4477	SCOPOLIA CARNIOLICA	A, H	The concentration of equivalent dry Scopolia carniolica in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4478	SCROPHULARIA NINGPOENSIS	A, H	
4479	SCROPHULARIA NODOSA	A, H	
4480	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4481	SCUTELLARIA BAICALENSIS	A, E, H	
4482	SCUTELLARIA BARBATA	A, H	
4483	SCUTELLARIA LATERIFLORA	A, E, H	
4484	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%.
4485	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%.
4486	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%.
4487	SECALE CEREALE	A, H	Gluten is a mandatory component of Secale cereale when the plant part is seed and the route of administration is other than topical and mucosal.
4488	SEDUM ACRE	A, H	
4489	SELAGINELLA TAMARISCINA	A, H	
4490	SELENICEREUS GRANDIFLORUS	A, E, H	
4491	SELENIUM	H	Only for use as an active homoeopathic ingredient. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4492	SELENOCYSTEINE	A	Selenium is a mandatory

			component of Selenocysteine for oral and sublingual use. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.'
4493	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.'
4494	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4495	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.
4496	SEMOLINA	E	
4497	SEMPERVIVUM TECTORUM	A, H	
4498	SENEGA ROOT DRY	A, H	
4499	SENEGA ROOT POWDER	A, H	
4500	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 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and

			- (LAX2) 'Prolonged use may cause serious bowel problems'.
4501	SENNA FRUIT ALEXANDRIAN DRY	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on

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

			dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4503	SENNA FRUIT TINNEVELLY DRY	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the

			chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the 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'.
4504	SENNA FRUIT TINNEVELLY POWDER	A, H	When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed

			as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4505	SENNA LEAF DRY	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna leaf dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the

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			following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4506	SENNA LEAF POWDER	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Leaf Powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek

			the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4507	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. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems';

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			and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect]. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' [or words to that effect]. When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine 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'.
4508	SENNA TORA	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna tora. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the

			medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4509	SEPIA	H	Only for use as an active homoeopathic ingredient. The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’

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			or 'Contains mollusc products'.
4510	SEQUOIA SEMPERVIRENS	A, H	
4511	SEQUOIADENDRON GIGANTEUM	A, H	
4512	SERENOA REPENS	A, H	
4513	SERINE	A, E	
4514	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4515	SESAME OIL	A, E, H	
4516	SESAME SEED	E	
4517	SESAMUM INDICUM	A, E, H	
4518	SETARIA ITALICA	A, H	
4519	SHARK CALCIUM CHONDROITIN SULFATE	A	
4520	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)
4521	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%.
4522	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4523	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%.
4524	SHARK-LIVER OIL	A, E	Vitamin A and Colecalciferol are

			mandatory components of Shark-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (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.'
4525	SHEA BUTTER	E	
4526	SHEA BUTTER ETHYL ESTERS	E	Shea butter ethyl esters must: (a) Only be used in topical medicines for dermal application; and

			(b) Not be included in medicines intended for use on broken skin. The total concentration of shea butter ethyl esters in the medicine must not be more than 30%.
4527	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4528	SHELLAC	E	
4529	SHEPHERD'S PURSE HERB DRY	A, H	
4530	SHEPHERD'S PURSE HERB POWDER	A, H	
4531	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%.
4532	SIGESBECKIA ORIENTALIS	A, E, H	
4533	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%.
4534	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%.
4535	SILICA SILYLATE	E	Only for use in topical medicines for dermal application.
4536	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.

4537	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4538	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).
4539	SILVER	H	Only for use as an active homoeopathic ingredient. When for external use, the total concentration of silver in the medicine must not be more than 1%. When for oral use: (a) the total concentration of silver in the medicine must not be more than 0.3%; and (b) the following warning statement is required on the medicine label: - 'Overuse may stain skin or mouth.' (or words to that effect).
4540	SILVER BEET	E, H	
4541	SILVER BOROSILICATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine should be no more than 0.6%. Silver is a mandatory component of Silver borosilicate when the route of administration is topical. The concentration of silver in the medicine must be no more than 1%.
4542	SILVER NITRATE	H	Only for use as an active

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			homoeopathic ingredient.
4543	SILYBUM MARIANUM	A, E, H	
4544	SIMABA CEDRON	A, H	
4545	SIMETHICONE	E	
4546	SIMMONDSIA CHINENSIS	A, E, H	
4547	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%.
4548	SINAPIS ARVENSIS	A, H	
4549	SINOMENIUM ACUTUM	A, H	
4550	SIPHONESTEGIA CHINENSIS	A, H	
4551	SIRAITIA GROSVENORII	A, E, H	
4552	SISYMBRIUM OFFICINALE	A, H	
4553	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%.
4554	SKIPJACK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of Skipjack-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.

			When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (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.'
4555	SLIPPERY ELM BARK DRY	A, H	
4556	SLIPPERY ELM BARK POWDER	A, E, H	
4557	SMILAX ARISTOLOCHIIFOLIA	A, H	
4558	SMILAX CHINA	A, H	
4559	SMILAX GLABRA	A, H	
4560	SMILAX OFFICINALIS	A, E, H	
4561	SMILAX ORNATA	A, E, H	
4562	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%.
4563	SODIUM ACETATE	E	
4564	SODIUM ACETYLATED	E	Only for use in topical medicines

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	HYALURONATE		for dermal 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%.
4565	SODIUM ACID CITRATE	A, E, H	When sodium acid citrate is used as an active ingredient, only for use in oral medicines.
4566	SODIUM ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.8%.
4567	SODIUM ACRYLATES CROSSPOLYMER-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.7 % (w/w).
4568	SODIUM ACRYLOYDIMETHYLTAURATE/ VP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% (w/w).
4569	SODIUM ALGINATE	E	
4570	SODIUM ASCORBATE	A, E, H	
4571	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%.

4572	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%.
4573	SODIUM BENZOATE	E	
4574	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
4575	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4576	SODIUM BICARBONATE	A, E	When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms. Medicines containing sodium bicarbonate for use as oral rehydration therapy are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.' c) the following warning statements are required on the medicine label: - (UOAD) 'Use only as directed.' - (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice (or words to that effect).'

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			- (DIAR3) 'If diarrhoea persists, seek medical advice.'
4577	SODIUM BISULFITE	E	
4578	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient. The total concentration of sodium bromide in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4579	SODIUM BUTYRATE	A, E	The route of administration for medicines that contain sodium butyrate must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 1200 mg sodium butyrate. The following warning statement (or words to the same effect) is required on the medicine label: - (ADULT) 'Adults only'.
4580	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4581	SODIUM CALCIUM EDETATE	E	When for oral use, sodium is a mandatory component of sodium calcium edetate. Sodium calcium edetate must only be included in medicines when: (a) the route of administration is limited to topical for dermal use; or (b) in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of sodium calcium edetate in the medicine must not exceed 0.32%. The total concentration of flavour proprietary excipient formulations containing sodium calcium edetate must not be more than 5% of the total medicine.
4582	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal

			application.
4583	SODIUM CARBONATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4584	SODIUM CARBONATE MONOHYDRATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4585	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%.
4586	SODIUM CARRAGEENAN	E	
4587	SODIUM CASEINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4588	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4589	SODIUM CHLORIDE	A, E, H	
4590	SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient ingredient: a) only for use in topical medicines for dermal application and not to be included in medicines intended for use in the

			eye; b) the concentration in the medicine must not be more than 0.001%. When used as an active ingredient: a) the route of administration must only be oral; b) the maximum daily dose must not provide more than 1,200 mg of sodium chondroitin sulfate; c) the following statements must be included on the medicine label: - (ADULT) 'Adults only' (or words to that effect); - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
4591	SODIUM CITRATE	A, E	When for use as an active ingredient, only for oral use.
4592	SODIUM CITRATE DIHYDRATE	A, E	When for use as an active ingredient, only for oral use.
4593	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%.
4594	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4595	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4596	SODIUM CYCLAMATE	E	
4597	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4598	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%.

4599	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4600	SODIUM ERYTHORBATE	E	
4601	SODIUM ETHYL HYDROXYBENZOATE	E	
4602	SODIUM FLUORIDE	A, E, H	Fluoride is a mandatory component of sodium fluoride. The route of administration must be limited to dental. The dosage form must be limited to pastes, powders and/or gels for dental hygiene. When used as an active ingredient, the medicine is subject to the following conditions: (a) only for use in combination with at least one other active ingredient; and (b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'
4603	SODIUM FUMARATE	E	
4604	SODIUM HYALURONATE	A, E	When for use as an excipient ingredient, sodium hyaluronate must only be used in medicines with a topical route of administration for dermal application. When for use as an active ingredient: (a) the molecular mass of sodium hyaluronate must be between 600 and 1600 kilodaltons; and (b) sodium hyaluronate must only

			be used in medicines when the route of administration is limited to: (i) topical for dermal application; or (ii) oral. When for use in a topical medicine for dermal application the concentration of sodium hyaluronate in the medicine must not exceed 2.0%. When for use as an active ingredient and the route of administration is oral: (a) the maximum recommended daily dose must not provide more than 200 milligrams sodium hyaluronate; (b) the recommended duration of use of the medicine must be limited to three months; and (c) the following warning statements (or words to the same effect) are required on the medicine label : - (ADULT) 'Adults only'; and - (PREGNT) ' Not recommended for use by pregnant and lactating women'.
4605	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4606	SODIUM HYDROXIDE	E	The concentration of sodium hydroxide in the medicine must not be more than 5%. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4607	SODIUM HYDROXYCITRATE	A	
4608	SODIUM HYDROXYETHYL ACRYLATE/ACRYLOYLDIMETHYL TAURATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

			The concentration in the medicine must be no more than 1.5%.
4609	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4610	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of sodium hypochlorite. The concentration of chlorine in the medicine must not be more than 4%.
4611	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4612	SODIUM LACTATE	E	
4613	SODIUM LAURETH SULFATE	E	
4614	SODIUM LAUROAMPHOACETATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4615	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%.
4616	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4617	SODIUM LAURYL PHOSPHATE	E	
4618	SODIUM LAURYL SULFATE	E	
4619	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4620	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4621	SODIUM MANNOSE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4622	SODIUM METABISULFITE	E	
4623	SODIUM METAPHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must not be more than 0.1%.
4624	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine must be no more than 2%.
4625	SODIUM METHYL HYDROXYBENZOATE	E	
4626	SODIUM MOLYBDATE DIHYDRATE	A	Only for use in oral medicines. Molybdenum is a mandatory component of Sodium molybdate dihydrate. The percentage of molybdenum from sodium molybdate dihydrate should be calculated based on the molecular weight of sodium molybdate dihydrate. The maximum daily dose of molybdenum from Sodium molybdate dihydrate must be no more than 125 micrograms.
4627	SODIUM MONOFLUOROPHOSPHATE	A	Fluoride is a mandatory component of sodium monofluorophosphate. The route of administration must be limited to dental. The dosage form must be limited to pastes, powders and/or gels for dental hygiene. When sodium monofluorophosphate is used as an active ingredient, it is subject to the following conditions: (a) only for use in combination with at least one other active

			ingredient; and (b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000 mg/kg, the following warning statements are required on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'
4628	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%.
4629	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4630	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4631	SODIUM PANTOTHENATE	A, E, H	
4632	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4633	SODIUM PERBORATE	A, H	Boron is a mandatory component of sodium perborate. When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron. When used in preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron from all ingredients in the product must not exceed 3500 mg/kg or 3500 mg/L or 0.35%. When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for

			internal use and/or oral application, one of the following warning statements is required on the label: - (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label: - (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label: - (BORON) 'Contains boron' (or words to that effect). When the medicine is for topical use for dermal application, the following warning statement is required on the label: - (BROKEN) 'Use on unbroken skin only' (or words to that effect).
4634	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.
4635	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4636	SODIUM POLYACRYLATE	E	Only for use in topical medicines

	STARCH		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%.
4637	SODIUM POLYMETAPHOSPHATE	E	
4638	SODIUM PROPIONATE	E	
4639	SODIUM PROPYL HYDROXYBENZOATE	E	
4640	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%.
4641	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.'
4642	SODIUM SELENATE DECAHYDRATE	A	Selenium is a mandatory component of sodium selenate decahydrate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should

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			not be exceeded.'
4643	SODIUM SELENITE	A, H	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: - (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.'
4644	SODIUM SELENITE PENTAHYDRATE	A	Selenium is a mandatory component of Sodium selenite pentahydrate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4645	SODIUM SILICATE	E	
4646	SODIUM STARCH GLYCOLLATE	E	
4647	SODIUM STARCH GLYCOLLATE TYPE A	E	
4648	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4649	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%.

4650	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%.
4651	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4652	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%.
4653	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4654	SODIUM SULFATE	A, E, H	When it is not intended to be a laxative, the following warning statement is required on the medicine label: - (LAX4) 'Substance may have a laxative effect'.
4655	SODIUM SULFATE DECAHYDRATE	A, E, H	When it is not intended to be a laxative, the following warning statement is required on the medicine label: - (LAX4) 'Substance may have a laxative effect'.
4656	SODIUM SULFITE	E	
4657	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application.
4658	SODIUM TRIPOLYPHOSPHATE	E	Only for use when the route of administration is topical for dermal application, mucous membrane (buccal mucosa) or dental. Not to be included in topical medicines intended for use in the eye.

			The concentration in the medicine must be no more than 5%.
4659	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.
4660	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.
4661	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%.
4662	SOLANUM MELONGENA	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum melongena. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4663	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.

4664	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.
4665	SOLIDAGO GIGANTEA	A, H	
4666	SOLIDAGO GIGANTEA MIS	A, E, H	
4667	SOLIDAGO VIRGAUREA	A, E, H	
4668	SOLUBLE MAIZE STARCH	E	
4669	SOLUBLE POTATO STARCH	E	
4670	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4671	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4672	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4673	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%.
4674	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4675	SOPHORA FLAVESCENS	A, E, H	
4676	SOPHORA TONKINENSIS	A, H	
4677	SORBIC ACID	E	
4678	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4679	SORBITAN MONO-OLEATE	E	
4680	SORBITAN MONOLAURATE	E	
4681	SORBITAN MONOSTEARATE	E	
4682	SORBITAN OLEATE	E	
4683	SORBITAN OLIVATE	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
4684	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%.
4685	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4686	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4687	SORBITAN STEARATE	E	
4688	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4689	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.
4690	SORBITOL SOLUTION (70 PER CENT) (CRYSTALLISING)	A, E	Sorbitol is a mandatory component of sorbitol solution (70 per cent) (crystallising). When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
4691	SORBITOL SOLUTION (70 PER CENT) (NON-CRYSTALLISING)	A, E	Sorbitol is a mandatory component of sorbitol solution (70 per cent) (non-crystallising).

			When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
4692	SORBUS AUCUPARIA	A, H	
4693	SORGHUM	E	
4694	SORGHUM VULGARE	A, H	
4695	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%.
4696	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%.
4697	SOY POLYSACCHARIDE	E	
4698	SOY PROTEIN	E	
4699	SOY STEROL	E	
4700	SOYA BEAN	E	
4701	SOYA BRAN	E	
4702	SOYA OIL	A, E, H	
4703	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%.
4704	SOYBEAN GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

			for use in the eye. The concentration in the medicine must be no more than 4%.
4705	SPARGANIUM STOLONIFERUM	A, H	
4706	SPARTIUM JUNCEUM	A, H	
4707	SPATHOLOBUS SUBERECTUS	A, H	
4708	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 to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.

4709	SPEARMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. Menthol is a mandatory component of spearmint oil terpeneless. When the medicine is for topical use for dermal application: i) the medicine must not be intended for use in the eye or on damaged skin; ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal

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			use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4710	SPHINGOLIPIDS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4711	SPIGELIA ANTHELMIA	A, H	
4712	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4713	SPIKE LAVENDER OIL	A, E, H	Camphor is a mandatory component of spike lavender oil. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

			- (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
4714	SPINACH	E	
4715	SPINACIA OLERACEA	A, E, H	
4716	SPIRODELA POLYRRHIZA	A, H	
4717	SPIRULINA	E	
4718	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use as an excipient for oral routes of administration.
4719	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use as an excipient for oral routes of administration.
4720	SPRUCE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4721	SQUALANE	E	Only for use in topical medicines for dermal application.
4722	SQUALENE	A, E	

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4723	SQUID OIL	A	Only for use in oral medicines. Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in combination with other ingredients in the medicine and be presented in a therapeutic dosage form for therapeutic use. The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
4724	SQUILL DRY	A, H	
4725	SQUILL INDIAN DRY	A, H	
4726	SQUILL INDIAN POWDER	A, H	
4727	SQUILL POWDER	A, H	
4728	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.'
4729	ST JOHN'S WORT HERB DRY	A, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4730	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.'
4731	STACHYS OFFICINALIS	A, E, H	

4732	STACHYS PALUSTRIS	A, H	
4733	STACHYURUS HIMALAICUS	A, H	
4734	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%.
4735	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4736	STAR ANISE OIL	A, E	When the total concentration of star anise oil in the medicine is more than 50%: (a) the nominal capacity of the container must not be more than 50 mL; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4737	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%.
4738	STARCH SODIUM OCTENYL SUCCINATE	E	
4739	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4740	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4741	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4742	STEARAMIDOETHYL	E	Only for use in topical medicines

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	DIETHYLAMINE		for dermal application.
4743	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4744	STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 2%. When the medicine is intended to be used on the eye, the medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4745	STEARETH-10	E	Only for use in topical medicines for dermal application.
4746	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%.
4747	STEARETH-2	E	Only for use in topical medicines for dermal application.
4748	STEARETH-20	E	Only for use in topical medicines for dermal application.
4749	STEARETH-21	E	Only for use in topical medicines for dermal application.
4750	STEARETH-5	E	Only for use in topical medicines for dermal application.
4751	STEARIC ACID	E	
4752	STEAROPTENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

4753	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%.
4754	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4755	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4756	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4757	STEARYL ALCOHOL	E	
4758	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.
4759	STEARYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4.5%. The medicine requires the following warning statements on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect) - (EYE) 'Avoid contact with eyes' (or words to that effect).
4760	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4761	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.

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4762	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%.
4763	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4764	STELLARIA CHAMAEJASME	A, H	
4765	STELLARIA DICHOTOMA	A, H	
4766	STELLARIA MEDIA	A, E, H	
4767	STEMONA JAPONICA	A, H	
4768	STEMONA SESSILIFOLIA	A, H	
4769	STENOTAPHRUM SECUNDATUM	A, H	
4770	STEPHANIA TETRANDA	A, H	
4771	STERCULIA	A, H	
4772	STERCULIA TRAGACANTHA	A, H	
4773	STERCULIA URENS	A, H	
4774	STEVIA REBAUDIANA	A, E, H	
4775	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4776	STILLINGIA SYLVATICA	A, H	
4777	STORAX PREPARED	A, E, H	
4778	STRAWBERRY	E	
4779	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%.
4780	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'.
4781	STREPTOCOCCUS THERMOPHILUS	A	
4782	STROBILANTHES CUSIA	A, H	
4783	STRONG AMMONIA SOLUTION	E	Ammonia is a mandatory component of strong ammonia solution. The concentration of ammonia in the medicine must be no more than 0.5%. When for internal use, the concentration in the medicine must be no more than 0.25%.
4784	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4785	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4786	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4787	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%.
4788	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%.
4789	STYPHNOLOBIUM JAPONICUM	A, E, H	

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4790	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%.
4791	STYRAX BENZOIN	A, E, H	
4792	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%.
4793	STYRAX PARALLELONEURUM	A, H	
4794	STYRAX TONKINENSIS	A, H	
4795	STYRENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. The total concentration of styrene in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4796	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4797	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%.
4798	SUBLIMED SULFUR	H	Only for use as an active

			homoeopathic ingredient.
4799	SUCCINIC ACID	E	
4800	SUCRALOSE	E	
4801	SUCROSE	E	
4802	SUCROSE ACETATE ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4803	SUCROSE ACETATE PALMITATE STEARATE	E	Only for use in topical medicines for dermal application and not intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
4804	SUCROSE COCOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
4805	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4806	SUCROSE LAURATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate.
4807	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.
4808	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4809	SUCROSE POLYCOTTONSEEDATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

			must be no more than 1%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with the eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4810	SUCROSE STEARATE	E	For use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When for topical use, the concentration in the medicine must be no more than 0.25%. For oral use as a manufacturing aid only. When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit.
4811	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%.
4812	SUDAN III	E	Permitted for use only as a colour for topical use.
4813	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).
4814	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of sugarcane.
4815	SULFATED CASTOR OIL	E	Only for use in topical medicines

			for dermal application.
4816	SULFATED LOW MOLECULAR WEIGHT FUCANS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.025%.
4817	SULFUR DIOXIDE	E	
4818	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4819	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%.
4820	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%.
4821	SULISOBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4822	SULISOBENZONE SODIUM	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).
4823	SUNFLOWER OIL	A, E, H	
4824	SUNFLOWER SEED	E, H	
4825	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4826	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
4827	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4828	SWEDE	E	
4829	SWEET ORANGE OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4830	SWEET POTATO	E	
4831	SWERTIA CHIRATA	A, H	
4832	SWIETENIA MAHOGANI	A, H	
4833	SYAGRUS ROMANZOFFIANA	A, E, H	

4834	SYMPHYOTRICHUM NOVI-BELGII	A, H	
4835	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%.
4836	SYMPLOCARPUS FOETIDUS	A, H	
4837	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4838	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.
4839	SYNTHETIC WAX	E	
4840	SYRINGA RETICULATA	A, H	
4841	SYRINGA VULGARIS	A, H	
4842	SYZYGIUM AROMATICUM	A, E, H	When the plant preparation is oil or distillate and the concentration of this oil or distillate in the product is greater than 25%, the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the plant preparation is oil or distillate, the concentration of this oil or distillate in the medicine is greater than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, a child resistant closure and restricted flow insert must be fitted on the container.

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			When the plant preparation is oil or distillate, the concentration of oil or distillate in the product is greater than 25% and the nominal capacity of the container is less than 15 millilitres, a restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate and the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of the oil or distillate and the concentration of oil or distillate in the product must not be greater than 25%.
4843	SYZYGIUM CUMINI	A, H	
4844	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%.
4845	TABEBUIA SERRATIFOLIA	A, E, H	
4846	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%.
4847	TAGETES MINUTA	A, E, H	
4848	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%.

4849	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4850	TALLOW	E	Only for use in topical medicines for dermal application.
4851	TALLOW GLYCERIDES	E	
4852	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%.
4853	TAMARIX APHYLLA	A, H	
4854	TAMARIX CHINENSIS	A, H	
4855	TAMARIX GALLICA	A, H	
4856	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.
4857	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4858	TANACETUM PARTHENIUM	A, E, H	
4859	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%.
4860	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4861	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.
4862	TANNIC ACID	E	
4863	TAPIOCA STARCH	E	
4864	TARAXACUM MONGOLICUM	A, E, H	
4865	TARAXACUM OFFICINALE	A, E, H	
4866	TARO	E	
4867	TARRAGON OIL	A, E, H	
4868	TARTARIC ACID	E	
4869	TARTRAZINE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4870	TARTRAZINE ALUMINIUM LAKE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4871	TASMANNIA LANCEOLATA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4872	TAURINE	A, E	
4873	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4874	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'.
4875	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4876	TERMINALIA CATAPPA	A, H	
4877	TERMINALIA CHEBULA	A, H	
4878	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 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 0.3%.
4879	TERMINALIA SERICEA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. Only for use when the plant part is root bark. Only methanol/water (90:10; V/V) extract of Terminalia sericea bark of the root is approved. The concentration in the medicine must be no more than 0.1%.
4880	TERPENE RESIN	E	Terpene resin must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical

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			application.
4881	TERPINEN-4-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4882	TERPINEOL	E	
4883	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%.
4884	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%.
4885	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%.
4886	TERPINYL BUTYRATE	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%.
4887	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%.
4888	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4889	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%.
4890	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%.
4891	TERT-BUTYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4892	TETRACLINIS ARTICULATA	A, E, H	
4893	TETRADECYL	E	Only for use in topical medicines

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	AMINOBUTYROYLVALYLAMINOBUTYRIC UREA TRIFLUOROACETATE		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%.
4894	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.
4895	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%.
4896	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%.
4897	TETRAHYDRO PARA-METHYLQUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4898	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%.
4899	TETRAHYDRODIFERULOYLMETHANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

			The concentration in the medicine must be no more than 0.1%.
4900	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%.
4901	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%.
4902	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%.
4903	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%.
4904	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%.
4905	TETRAHYDROXYPROPYL	E	Only for use in topical medicines

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	ETHYLENEDIAMINE		for dermal application.
4906	TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4907	TETRAPANAX PAPYRIFER	A, H	
4908	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4909	TETRASODIUM PYROPHOSPHATE	E	
4910	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4911	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4912	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4913	THAPSIA GARGANICA	A, H	
4914	THAUMATIN	E	
4915	THEASPIRANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4916	THEMEDA TRIANDRA	A, H	

4917	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma cacao. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine.' - (CAFFPREG) ‘Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.’ When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or

			oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
4918	THEOBROMA OIL	A, E, H	
4919	THIAMINE	A, E	
4920	THIAMINE HYDROCHLORIDE	A, E	
4921	THIAMINE NITRATE	A, E	
4922	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%.
4923	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%.
4924	THLASPI ARVENSE	A, E, H	
4925	THREONINE	A, E	
4926	THUJA OCCIDENTALIS	A, H	
4927	THUJA PLICATA	A, E, H	
4928	THYME HERB DRY	A, E, H	
4929	THYME OIL	A, E, H	When the concentration of Thyme oil in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the warning statement: - (CHILD) 'Keep out of reach of children' (or words to that effect).

4930	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.
4931	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.
4932	THYMUS CAPITATUS	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4933	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4934	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).

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4935	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).
4936	THYMUS VULGARIS	A, E, H	When the plant preparation is oil or distillate, and the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%: (a) the nominal capacity of the container must not be more than 25 millilitres; (b) a restricted flow insert must be fitted on the container; and (c) the following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4937	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).
4938	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).
4939	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4940	TILACTASE	A	Must be derived from Aspergillus oryzae and comply with the relevant USP monograph.
4941	TILIA CORDATA	A, E, H	
4942	TILIA PLATYPHYLLOS	A, E, H	
4943	TILIA TOMENTOSA	A, H	
4944	TILIA X VULGARIS	A, E, H	
4945	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%.
4946	TIN	H	Only for use as an active homoeopathic ingredient.
4947	TINOSPORA CORDIFOLIA	A, H	
4948	TINOSPORA SINENSIS	A, H	
4949	TITANIUM DIOXIDE	A, E	For use as an active ingredient only in sunscreens for dermal application. The concentration in sunscreens must be no more than 25%. For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. Not to be included in medicines intended for use in the eye. When used in primary sunscreen

			products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4950	TOCOCYSTEAMIDE	E	Only for use in topical medicines for dermal 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%.
4951	TOCOFERSOLAN	E	Only for oral and topical use. When for oral use, the concentration in the medicine must be no more than 10% w/w. When used in topical medicines for dermal application, it is 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 0.1%
4952	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%.
4953	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%

4954	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4955	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%.
4956	TOLU BALSAM	A, E, H	
4957	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%.
4958	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%.
4959	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%.
4960	TOMATO	E	
4961	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%.

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4962	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%.
4963	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%.
4964	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4965	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.
4966	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4967	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4968	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4969	TRACHYSPERMUM AMMI	A, E	Only for use in oral medicines when the plant part is fruit or seed. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended

			for use by pregnant and lactating women' (or words to that effect) - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect). Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4970	TRAGACANTH	A, E	
4971	TRAMETES VERSICOLOR	A, H	
4972	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4973	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%.
4974	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.
4975	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%.

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4976	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%.
4977	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%.
4978	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%.
4979	TRANS-2-HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4980	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%.
4981	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%.
4982	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%.
4983	TRANS-2-HEXENYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4984	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%.
4985	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.

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4986	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%.
4987	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%.
4988	TRANS-4-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4989	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%.
4990	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%.
4991	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%.
4992	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of treacle.
4993	TREEMOSS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. When included in a medicine for use on the lips the concentration of treemoss absolute must be no more than 0.02%. When for dermal use or use on the hair the concentration of treemoss absolute must be no more than 0.1% The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
4994	TREFRIW WELLS MINERAL WATER	A	When for internal use, iron is a mandatory component of Trefriw Wells mineral water. Solid dosage forms containing more than 5 milligrams of elemental iron in each dosage unit are required to have a child resistant closure. Liquid Preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. Only able to be used when presented in single use sachets for therapeutic use as an iron supplement.
4995	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.

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4996	TREMELLA FUCIFORMIS	A, H	
4997	TRIACETIN	E	
4998	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4999	TRIADICA SEBIFERA	A, H	
5000	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.
5001	TRIBASIC SODIUM PHOSPHATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
5002	TRIBEHENIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
5003	TRIBEHENIN PEG-20 ESTERS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
5004	TRIBULUS TERRESTRIS	A, E, H	
5005	TRIBUTYL ACETYLCITRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

			fragrance concentration in a medicine must be no more than 1%.
5006	TRICALCIUM PHOSPHATE	E	
5007	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%.
5008	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%.
5009	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
5010	TRICHLOROMETHYLPHENYLCARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5011	TRICHODERMA VIRIDE	A, E, H	
5012	TRICHOSANTHES KIRILOWII	A, E, H	
5013	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
5014	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%.
5015	TRIDECANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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			fragrance concentration in a medicine must be no more than 1%.
5016	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
5017	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%.
5018	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%.
5019	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
5020	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%.
5021	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%.
5022	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
5023	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.

5024	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%.
5025	TRIETHYL CITRATE	E	
5026	TRIETHYLENE GLYCOL	E	
5027	TRIFOLIUM PRATENSE	A, E, H	
5028	TRIFOLIUM REPENS	A, H	
5029	TRIGONELLA FOENUM-GRAECUM	A, E, H	
5030	TRIHYDROXYPALMITAMIDOHYDROXYPROPYL 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%.
5031	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
5032	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
5033	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%.
5034	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%.
5035	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
5036	TRILAURIN	E	Only for use in topical medicines for dermal application.

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5037	TRILISA ODORATISSIMA	A, H	
5038	TRILLIUM ERECTUM	A, H	
5039	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%.
5040	TRIMETHYL HYDROXYPENTYL 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%.
5041	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%.
5042	TRIMETHYL-BICYCLO-HEPTANE-SPIROCYCLOHEXENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5043	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%.
5044	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%.
5045	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5046	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%.
5047	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5048	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient. The total concentration of trinitrophenol in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5049	TRIOCTANOIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5050	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%.
5051	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%.
5052	TRIOSTEUM PERFOLIATUM	A, H	
5053	TRIOXAUNDECANEDIOIC ACID	E	
5054	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%.
5055	TRIPEPTIDE-1	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
5056	TRIS-BIPHENYL TRIAZINE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used topically, the dosage form must not be spray. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
5057	TRISILOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 40%.
5058	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
5059	TRISODIUM ETHYLENEDIAMINE DISUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

			The concentration in the medicine must be no more than 0.2%.
5060	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%.
5061	TRISTEARIN	E	
5062	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.
5063	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.
5064	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%.
5065	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5066	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
5067	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).
5068	TROLLIUS CHINENSIS	A, H	
5069	TROMETAMOL	E	
5070	TROMETAMOL HYDROCHLORIDE	E	
5071	TROPAEOLUM MAJUS	A, E, H	
5072	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5073	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%.
5074	TSUGA CANADENSIS	A, H	
5075	TULIPA EDULIS	A, H	Colchicine is a mandatory component of Tulipa edulis. The concentration of colchicine in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
5076	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5077	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%.
5078	TURNIP	E	
5079	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than 25%.
5080	TYPHA ANGUSTIFOLIA	A, H	
5081	TYPHA LATIFOLIA	A, H	
5082	TYPHONIUM GIGANTEUM	A, H	
5083	TYROSINE	A, E	