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**
3647	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%.
3648	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%.
3649	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

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			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3650	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%.
3651	PAEONIA LACTIFLORA	A, E, H	
3652	PAEONIA OBOVATA	A, H	
3653	PAEONIA SUFFRUTICOSA	A, E, H	
3654	PAEONIA VEITCHII	A, H	
3655	PALIURUS SPINA-CHRISTI	A, H	
3656	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3657	PALM FRUIT OIL	A, E, H	
3658	PALM GLYCERIDES	E	
3659	PALM KERNEL OIL	A, E, H	
3660	PALM TOCOTRIENOLS COMPLEX	A, H	
3661	PALMARIA PALMATA	A, H	
3662	PALMAROSA OIL	A, E, H	
3663	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.'
3664	PALMITIC ACID	E	
3665	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3666	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%.
3667	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%
3668	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%.
3669	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%.
3670	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%.
3671	PANAX GINSENG	A, E, H	
3672	PANAX JAPONICUS	A, H	
3673	PANAX NOTOGINSENG	A, H	
3674	PANAX PSEUDOGINSENG	A, H	
3675	PANAX QUINQUEFOLIUS	A, H	
3676	PANICUM MILIACEUM	A, H	
3677	PANTETHINE	E	Only for use in topical medicines for dermal application.
3678	PANTHENOL	A, E	
3679	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3680	PANTOLACTONE	E	
3681	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3682	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%.
3683	PAPAIN	A, E	
3684	PAPER	E	Only for use in topical medicines for dermal application.
3685	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%.
3686	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%.
3687	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%.
3688	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%.
3689	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%.

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3690	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%.
3691	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%.
3692	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.
3693	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%.
3694	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%.
3695	PARA-HYDROXYBENZOIC ACID	E	
3696	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%.
3697	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%.
3698	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%.
3699	PARA-METHYL	E	Permitted for use only in

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	DIMETHYLBENZYL CARBINOL		combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3700	PARA-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.
3701	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%.
3702	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%.
3703	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%.
3704	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%.
3705	PARAMERIA LAEVIGATA	A, H	
3706	PARIETARIA JUDAICA	A, H	
3707	PARIS POLYPHYLLA	A, H	
3708	PARIS QUADRIFOLIA	A, H	
3709	PARSLEY	E, H	
3710	PARSLEY HERB DRY	A, E, H	
3711	PARSLEY HERB OIL	A, E, H	
3712	PARSLEY HERB POWDER	A, E, H	
3713	PARSLEY SEED OIL	A, E, H	
3714	PARTHENOCISSUS TRICUSPIDATA	A, H	
3715	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.

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3716	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%.
3717	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%.
3718	PASPALUM NOTATUM	A, H	
3719	PASSIFLORA CAERULEA	A, H	
3720	PASSIFLORA EDULIS	E	
3721	PASSIFLORA HERB DRY	A, H	
3722	PASSIFLORA INCARNATA	A, E, H	
3723	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%.
3724	PATENT BLUE V	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3725	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.

3726	PATRINIA SCABIOSIFOLIA	A, H	
3727	PATRINIA VILLOSA	A, H	
3728	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).
3729	PAULLINIA PINNATA	A, H	
3730	PAWPAW	E	
3731	PEA	E	
3732	PEA STARCH	E	
3733	PEACH	E	
3734	PEANUT	E	
3735	PEAR	E	
3736	PECAN	E	
3737	PECTIN	A, E	
3738	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%.

3739	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3740	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3741	PEG-12 DILAURATE	E	
3742	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%.
3743	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3744	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3745	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3746	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3747	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%.
3748	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal

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			application.
3749	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3750	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3751	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3752	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).
3753	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3754	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3755	PEG-35 CASTOR OIL	E	
3756	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.

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

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3764	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3765	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3766	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%.
3767	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3768	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%.
3769	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%.
3770	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.

3771	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3772	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3773	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3774	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3775	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%.
3776	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%.
3777	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%.
3778	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal

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			application.
3779	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.
3780	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3781	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3782	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%.
3783	PEG/PPG-14/7 DIMETHYL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 7%.
3784	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%.
3785	PELARGONIUM GRAVEOLENS	A, E, H	
3786	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%.
3787	PELTIGERA CANINA	A, H	
3788	PENICILLIUM EXPANSUM	A, H	
3789	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.
3790	PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

			medicine must be no more than 0.018%
3791	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%.
3792	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3793	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%.
3794	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%.
3795	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%.
3796	PENTYLENE GLYCOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3797	PEPPER BLACK	E, H	
3798	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%.
3799	PEPPER WHITE	E, H	
3800	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

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			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.
3801	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.
3802	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

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			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.
3803	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.
3804	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:

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			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 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

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			internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3806	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3807	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%.
3808	PERILLA FRUTESCENS	A, E, H	
3809	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%.
3810	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%.
3811	PERMETHRIN	E	The total concentration of permethrin in the medicine must not be more than 2%.

3812	PERSEA AMERICANA	A, E, H	
3813	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%.
3814	PERSICARIA CHINENSIS	A, H	
3815	PERSICARIA TINCTORIA	A, H	
3816	PERSIMMON	E	
3817	PERU BALSAM	A, E, H	
3818	PERU BALSAM OIL	A, E, H	
3819	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%
3820	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%.
3821	PETITGRAIN OIL CITRONNIER	E	Permitted for use only in combination with other

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			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%.
3822	PETITGRAIN OIL PARAGUAY	A, E, H	When used internally, oxedrine is a mandatory component of petitgrain oil paraguay. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3823	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%.
3824	PETROSELINUM CRISPUM	A, E, H	
3825	PEUCEDANUM PRAERUPTORUM	A, E, H	
3826	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).
3827	PHALARIS ARUNDINACEA	A, H	
3828	PHALARIS CANARIENSIS	A, H	
3829	PHASEOLUS COCCINEUS	A, H	
3830	PHASEOLUS VULGARIS	A, H	
3831	PHELLINUS ROBINIAE	A, E, H	
3832	PHELLODENDRON AMURENSE	A, E, H	
3833	PHELLODENDRON CHINENSE	A, H	
3834	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3835	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%.
3836	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%.
3837	PHENETHYL ALCOHOL	E	Permitted for use only: a) in topical medicines for dermal application; and

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			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%.
3838	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%.
3839	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%
3840	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%.
3841	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%.
3842	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%.
3843	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%.
3844	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%.
3845	PHENOL	E	Only for use in topical medicines for dermal application. The concentration of phenol in the medicine must be no more than 1%.
3846	PHENOXYACETALDEHYDE	E	Permitted for use only in

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			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%.
3847	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The concentration of phenoxyethanol in the preparation must not exceed 15%.
3848	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%.
3849	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
3850	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3851	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3852	PHENYLACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3853	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%.
3854	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%.
3855	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%.
3856	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

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			pregnant'.
3857	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).
3858	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%.
3859	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%.
3860	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%.
3861	PHENYLETHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3862	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%.
3863	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%.
3864	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%.

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3865	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%.
3866	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%.
3867	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%.
3868	PHLEUM PRATENSE	A, H	
3869	PHLOXINE B	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3870	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3871	PHOENIX DACTYLIFERA	A, E, H	
3872	PHOSPHATIDYL CHOLINE	E	
3873	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%.
3874	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3875	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%.
3876	PHOTINIA SERRULATA	A, H	
3877	PHRAGMITES AUSTRALIS	A, H	
3878	PHYLLANTHUS AMARUS	A, H	
3879	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
3880	PHYLLOSTACHYS NIGRA	A, E, H	
3881	PHYSALIS ALKEKENGI	A, H	
3882	PHYSALIS PUBESCENS	A, H	
3883	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
3884	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%.
3885	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.

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3886	PHYTOMENADIONE	A, E	
3887	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%.
3888	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%.
3889	PICEA ABIES	A, H	
3890	PICEA MARIANA	A, H	
3891	PICRASMA EXCELSA	A, E, H	
3892	PICRORRHIZA KURROA	A, E, H	
3893	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%.
3894	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%.
3895	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%.
3896	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3897	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3898	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3899	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3900	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.
3901	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3902	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3903	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.
3904	PILOCARPUS JABORANDI	A, H	Pilocarpine is a mandatory component of Pilocarpus jaborandi. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3905	PILOCARPUS MICROPHYLLUS	A, H	Pilocarpine is a mandatory component of Pilocarpus microphyllus. The concentration of pilocarpine in the medicine

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			must be no more than 0.025%.
3906	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%.
3907	PIMENTA FRUIT OIL	A, E, H	
3908	PIMENTA LEAF OIL	A, E, H	
3909	PIMENTA OFFICINALIS	A, E, H	
3910	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'.
3911	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).
3912	PIMPINELLA SAXIFRAGA	A, E, H	
3913	PINE NEEDLE OIL SCOTCH	A, E, H	
3914	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%.
3915	PINE OIL AROMATIC	A, E, H	
3916	PINE OIL PUMILIO	A, E, H	
3917	PINEAPPLE	E	
3918	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%.
3919	PINELLIA TERNATA	A, H	

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3920	PINUS CONTORTA	A, E, H	
3921	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%.
3922	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%.
3923	PINUS MONTICOLA	A, E, H	
3924	PINUS MUGO	A, E, H	
3925	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%.
3926	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%.
3927	PINUS PONDEROSA	A, E, H	
3928	PINUS RADIATA	A, E, H	
3929	PINUS STROBUS	A, E, H	
3930	PINUS SYLVESTRIS	A, E, H	
3931	PINUS TABULIFORMIS	A, E, H	
3932	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%.
3933	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%.
3934	PIPER CHABA	A, E, H	
3935	PIPER CUBEBA	A, E, H	
3936	PIPER KADSURA	A, E, H	
3937	PIPER LONGUM	A, E, H	
3938	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 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.
3939	PIPER NIGRUM	A, E, H	
3940	PIPER SARMENTOSUM	A, E, H	
3941	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%.
3942	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%.
3943	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%.
3944	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%.
3945	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application.
3946	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.

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3947	PISCIDIA PISCIPULA	A, E, H	
3948	PISTACIA LENTISCUS	A, E, H	
3949	PISUM SATIVUM	A, E, H	
3950	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3951	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).
3952	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).
3953	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).
3954	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).
3955	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).
3956	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).
3957	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).
3958	PLATANUS OCCIDENTALIS	A, E, H	
3959	PLATANUS RACEMOSA	A, H	
3960	PLATANUS × HISPANICA	A, H	
3961	PLATYCODON GRANDIFLORUS	A, E, H	
3962	PLECTRANTHUS BARBATUS	A, E, H	
3963	PLICATONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3964	PLUM	E	
3965	PLUMBAGO EUROPAEA	A, H	
3966	PLUMERIA ALBA	A, E, H	
3967	PLUMERIA RUBRA	A, E, H	
3968	POA NEMORALIS	A, H	
3969	POA PRATENSIS	A, H	
3970	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%.
3971	POGOSTEMON CABLIN	A, E, H	
3972	POLACRILIN	E	
3973	POLACRILIN POTASSIUM	E	
3974	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).
3975	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.
3976	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

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			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.
3977	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 maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
3978	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).
3979	POLOXAMER	E	Only for use in topical medicines for dermal application.
3980	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%.

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3981	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%.
3982	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%.
3983	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%.
3984	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%.
3985	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%.
3986	POLYACRYLIC ACID	E	
3987	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3988	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%.
3989	POLYBUTADIENE	E	Only for use as part of an adhesive in topical medicines for dermal application.
3990	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3991	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%.
3992	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%.
3993	POLYDECENE	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 6%.
3994	POLYDEXTROSE	E	
3995	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%.
3996	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%
3997	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%.
3998	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%.
3999	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%.
4000	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%.
4001	POLYETHYLENE	E	
4002	POLYGALA CHINENSIS	A, H	
4003	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.
4004	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
4005	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
4006	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%.
4007	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%.
4008	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%.
4009	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
4010	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%.
4011	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%.
4012	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.

4013	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%.
4014	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4015	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%.
4016	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%.
4017	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%.
4018	POLYGLYCERYL-3 POLYRICINOLEATE	E	
4019	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application and not to be

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	CROSSPOLYMER		included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4020	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%.
4021	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%.
4022	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
4023	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%.
4024	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
4025	POLYGONATUM MULTIFLORUM	A, H	
4026	POLYGONATUM OFFICINALE	A, H	
4027	POLYGONATUM SIBIRICUM	A, E, H	

4028	POLYGONUM AVICULARE	A, E, H	When used as an excipient, the medicine is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. When used as an excipient, the concentration in the medicine must be no more than 0.16%.
4029	POLYGONUM BISTORTA	A, H	
4030	POLYGONUM ODORATUM	A, H	
4031	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
4032	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.
4033	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
4034	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%.

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4035	POLYMETHACRYLIC ACID	E	
4036	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%.
4037	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%.
4038	POLYPORUS UMBELLATUS	A, H	
4039	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
4040	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%.
4041	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal

			application.
4042	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4043	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%.
4044	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
4045	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
4046	POLYQUATERNIUM-37	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4047	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%.
4048	POLYQUATERNIUM-44	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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			for use in the eye. The concentration in the medicine must be no more than 0.3%.
4049	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%.
4050	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
4051	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%
4052	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%.
4053	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).
4054	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%.
4055	POLYSORBATE 20	E	
4056	POLYSORBATE 40	E	
4057	POLYSORBATE 60	E	
4058	POLYSORBATE 65	E	
4059	POLYSORBATE 80	E	
4060	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4061	POLYSTYRENE	E	Only for use as part of an adhesive in topical medicines for dermal application.
4062	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%.
4063	POLYURETHANE-34	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 or on damaged skin. The concentration in the medicine must be no more than 2% in spray applications and 6% in non-spray applications.
4064	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%.
4065	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4066	POLYVINYL ACETATE PHTHALATE	E	
4067	POLYVINYL ALCOHOL	E	
4068	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4069	POMEGRANATE	E	
4070	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4071	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.
4072	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%.
4073	PONTEDERIA CRASSIPES	A, H	
4074	POPPY SEED	E, H	
4075	POPPY SEED OIL	E, H	
4076	POPULUS ALBA	A, H	
4077	POPULUS BALSAMIIFERA	A, E, H	
4078	POPULUS CANDICANS	A, H	
4079	POPULUS DELTOIDES	A, H	
4080	POPULUS NIGRA	A, H	
4081	POPULUS TREMULA	A, H	
4082	POPULUS TREMULOIDES	A, H	
4083	PORCINE	H	Only for use as an active homoeopathic ingredient.
4084	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%.
4085	PORTULACA OLERACEA	A, E, H	
4086	POTABLE WATER	E	
4087	POTASSIUM ACETATE	E	
4088	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4089	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4090	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4091	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.

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4092	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.
4093	POTASSIUM ASPARTATE DIHYDRATE	A, E, H	If used as an active ingredient and the preparation is intended as a mineral supplementation, potassium is a mandatory component of Potassium aspartate dihydrate. The percentage of potassium from potassium aspartate dihydrate should be calculated based on the molecular weight of potassium aspartate dihydrate.
4094	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.
4095	POTASSIUM BICARBONATE	E	
4096	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%.
4097	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.
4098	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4099	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

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			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%.
4100	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.
4101	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%.
4102	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%.
4103	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4104	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.
4105	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.
4106	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.
4107	POTASSIUM HYDROXYCITRATE	A, H	
4108	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.
4109	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%.
4110	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%.
4111	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%.
4112	POTASSIUM NITRATE	A, H	Only for dental use. The concentration in the medicine must be no more than 5%.
4113	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.
4114	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%.
4115	POTASSIUM SORBATE	E	
4116	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%.
4117	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4118	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.

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4119	POTATO STARCH	E	
4120	POTENTILLA ANSERINA	A, H	
4121	POTENTILLA CHINENSIS	A, H	
4122	POTENTILLA DISCOLOR	A, H	
4123	POTENTILLA ERECTA	A, E, H	
4124	POTENTILLA REPTANS	A, H	
4125	POTERIUM OFFICINALE	A, E, H	
4126	POTERIUM SANGUISORBA	A, H	
4127	POVIDONE	E	
4128	POWDERED CELLULOSE	E	
4129	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%.
4130	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%.
4131	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%.
4132	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%.
4133	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%.
4134	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4135	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%.
4136	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4137	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%.
4138	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4139	PPG-3 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal

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			application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4140	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4141	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4142	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4143	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%.
4144	PREGELATINISED MAIZE STARCH	E	
4145	PREGELATINISED POTATO STARCH	E	
4146	PREGELATINISED RICE STARCH	E	
4147	PREGELATINISED STARCH	E	
4148	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4149	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%.
4150	PRICKLY ASH BARK DRY	A, H	
4151	PRICKLY ASH BARK POWDER	A, H	
4152	PRIMULA VERIS	A, E, H	
4153	PRIMULA VULGARIS	A, E, H	
4154	PRINSEPIA UNIFLORA	A, H	
4155	PROBOSCIDEA PARVIFLORA	A, H	
4156	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%.
4157	PROLINE	A, E	
4158	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%.
4159	PROPANE	E	Only for use as an excipient propellant ingredient.
4160	PROPANEDIOL	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%.
4161	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%.
4162	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%.
4163	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%.
4164	PROPIONYLLEVOCARNITINE HYDROCHLORIDE	A, H	
4165	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.'
4166	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.'
4167	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 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 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.'
4169	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.'
4170	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.'
4171	PROPYL ACETATE	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4172	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%.
4173	PROPYL GALLATE	E	
4174	PROPYL HYDROXYBENZOATE	E	
4175	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4176	PROPYLENE GLYCOL	E	
4177	PROPYLENE GLYCOL ALGINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4178	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%.
4179	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%.
4180	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4181	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4182	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4183	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%.
4184	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4185	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4186	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4187	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4188	PROSOPIS JULIFLORA	A, H	
4189	PROTEASE	A	Must be derived from Aspergillus oryzae or Aspergillus niger.

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4190	PROTEIN HYDROLYSATE	E	
4191	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%.
4192	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%.
4193	PRUNELLA VULGARIS	A, H	
4194	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%.
4195	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%.

4196	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%. 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 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%.
4198	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%.
4199	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

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			1 microgram/kg or 1 microgram/L or 0.0000001%.
4200	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%.
4201	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%.
4202	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%.

4203	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%.
4204	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%.
4205	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%.
4206	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

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			microgram/L or 0.0000001%.
4207	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%.
4208	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%.
4209	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4210	PSEUDOCYDONIA SINENSIS	A, H	
4211	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4212	PSEUDOTSUGA MENZIESII	A, H	
4213	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4214	PSIDIUM GUAJAVA	A, E, H	
4215	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4216	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).
4217	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).
4218	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).
4219	PTELEA TRIFOLIATA	A, H	
4220	PTEROCARPUS MARSUPIUM	A, H	
4221	PTEROCARPUS SANTALINUS	A, E, H	
4222	PUERARIA LOBATA	A, E, H	
4223	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4224	PULLULAN	E	
4225	PUMICE	E	
4226	PUMPKIN	E	
4227	PUMPKIN SEED	E, H	
4228	PUMPKIN SEED OIL	E, H	
4229	PUNICA GRANATUM	A, E, H	
4230	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4231	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).

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4232	PURIFIED SILICEOUS EARTH	E, H	
4233	PURIFIED TALC	E	
4234	PURIFIED WATER	E	
4235	PVM/MA COPOLYMER	E	
4236	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4237	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4238	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4239	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).
4240	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 requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for supply before 1 March 2023.

		(a) The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. (b) If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (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].' The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (c) 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. (d) If the maximum recommended daily dose of the

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			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].'
4241	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 requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for supply before 1 March 2023. (a) The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. (b) If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (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].'

			The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (c) 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. (d) 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	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 requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for supply before 1 March 2023. (a) The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. (b) If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (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].' The requirements specified in paragraphs (c) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (c) 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. (d) 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	PYROGLUTAMIC ACID	E	
4244	PYROLA DECORATA	A, H	
4245	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%.
4246	PYRROSIA LINGUA	A, H	
4247	PYRROSIA PETIOLOSA	A, H	
4248	PYRROSIA SHEARERI	A, H	
4249	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%.
4250	PYRUS PYRIFOLIA	A, H	Beta-arbutin is a mandatory component of Pyrus pyrifolia. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
4251	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%.
4252	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%.
4253	QUASSIA AMARA	A, E, H	
4254	QUASSIA WOOD JAMAICAN DRY	A, H	
4255	QUASSIA WOOD JAMAICAN POWDER	A, H	
4256	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4257	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4258	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4259	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.
4260	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.

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			The concentration in the medicine must be no more than 2.5%.
4261	QUERCETIN	A	
4262	QUERCETIN DIHYDRATE	A	
4263	QUERCUS ACUTISSIMA	A, H	
4264	QUERCUS ALBA	A, E, H	
4265	QUERCUS PALUSTRIS	A, H	
4266	QUERCUS ROBUR	A, H	
4267	QUERCUS RUBRA	A, H	
4268	QUERCUS VIRGINIANA	A, H	
4269	QUILLAIA DRY	A, H	
4270	QUILLAIA POWDER	A, E, H	
4271	QUILLAJA SAPONARIA	A, H	
4272	QUINCE	E	
4273	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.
4274	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.
4275	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4276	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4277	QUISQUALIS INDICA	A, H	
4278	R-ALPHA LIPOIC ACID	A	
4279	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%.
4280	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:

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			- (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.
4281	RADISH	E	
4282	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%.
4283	RANUNCULUS BULBOSUS	A, H	
4284	RANUNCULUS FICARIA	A, H	
4285	RANUNCULUS TERNATUS	A, H	
4286	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%.
4287	RAPHANUS SATIVUS	A, H	
4288	RASPBERRY	E	
4289	RASPBERRY BRANDY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4290	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%.
4291	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%.
4292	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%.
4293	RAUWOLFIA SERPENTINA	A, H	The concentration of equivalent dry Rauwolfia serpentina in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.

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4294	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%.
4295	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%.
4296	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%.
4297	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%.
4298	RED ANT	H	Only for use as an active homoeopathic ingredient.
4299	RED CLOVER FLOWER DRY	A, H	
4300	RED CLOVER FLOWER POWDER	A, H	
4301	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4302	RED DEER	A	
4303	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4304	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4305	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.

4306	REHMANNIA GLUTINOSA	A, E, H	
4307	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%.
4308	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%.
4309	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%.
4310	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).';

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			- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)'; and - (CHILD2) 'Not suitable for children'.
4311	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.'
4312	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.'

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4313	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.'
4314	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical

			medicines for dermal application.
4315	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%.
4316	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).

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			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'.
4317	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'.
4318	RHATANY ROOT DRY	A, H	

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4319	RHATANY ROOT POWDER	A, H	
4320	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'.
4321	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'.
4322	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'.
4323	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 cause serious bowel problems'.
4324	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4325	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%.
4326	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%.
4327	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.
4328	RHODODENDRON AUREUM	A, H	
4329	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%.
4330	RHODODENDRON GROENLANDICUM	A, H	
4331	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of

			the dry herbal material.
4332	RHUBARB	E, H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhubarb. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may

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			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'.
4333	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'.
4334	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'.
4335	RHUS AROMATICA	A, E, H	
4336	RHUS CHINENSIS	A, H	
4337	RHUS GLABRA	A, E, H	
4338	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4339	RIBES GROSSULARIA	A, E, H	
4340	RIBES NIGRUM	A, E, H	
4341	RIBOFLAVIN	A, E	
4342	RIBOFLAVIN SODIUM PHOSPHATE	A, E	
4343	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4344	RIBOFLAVINE	A, E	
4345	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4346	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4347	RIBOSE	A	Only for use in oral medicines.
4348	RICE	E	
4349	RICE BRAN	E	
4350	RICE BRAN OIL	E	
4351	RICE BRAN WAX	A, E, H	
4352	RICE STARCH	E	
4353	RICE VINEGAR	E	
4354	RICE WINE	E	Ethanol is a mandatory component of rice wine.
4355	RICINOLEIC ACID	E	Only for use in topical medicines for dermal

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			application.
4356	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4357	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.
4358	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4359	ROSA ARVENSIS	A, E, H	
4360	ROSA CANINA	A, E, H	
4361	ROSA CYMOSA	A, E, H	
4362	ROSA EGLANTERIA	A, E, H	
4363	ROSA GALLICA	A, E, H	
4364	ROSA LAEVIGATA	A, E, H	
4365	ROSA MULTIFLORA	A, E, H	
4366	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%.
4367	ROSA RUGOSA	A, E, H	
4368	ROSA VILLOSA	A, E, H	
4369	ROSA X CENTIFOLIA	A, E, H	
4370	ROSA X DAMASCENA	A, E, H	
4371	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%.
4372	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%.
4373	ROSE FRUIT FRESH	A, E, H	
4374	ROSE HIP	E	
4375	ROSE OIL	A, E, H	
4376	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%.
4377	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%.
4378	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.
4379	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'.
4380	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'.
4381	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

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			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	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4383	RUBIA CORDIFOLIA	A, H	
4384	RUBIA TINCTORUM	A, H	
4385	RUBUS CHINGII	A, H	
4386	RUBUS CORCHORIFOLIUS	A, H	
4387	RUBUS COREANUS	A, E, H	
4388	RUBUS FRUTICOSUS	A, E, H	
4389	RUBUS IDAEUS	A, E, H	
4390	RUBUS OCCIDENTALIS	A, E, H	
4391	RUBUS PARVIFOLIUS	A, H	
4392	RUBUS ROSIFOLIUS	A, H	
4393	RUDBECKIA HIRTA	A, H	
4394	RUE OIL	A, H	
4395	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%.
4396	RUMEX ACETOSA	A, H	
4397	RUMEX ACETOSELLA	A, H	
4398	RUMEX CONGLOMERATUS	A, H	
4399	RUMEX CRISPUS	A, E, H	
4400	RUMEX PULCHER	A, H	

4401	RUMEX SCUTATUS	A, H	
4402	RUSCUS ACULEATUS	A, H	
4403	RUTA GRAVEOLENS	A, E, H	
4404	RUTOSIDE	A, E	
4405	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4406	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.
4407	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%.
4408	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.
4409	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%.
4410	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%.
4411	SACCHARIN	E	
4412	SACCHARIN SODIUM	E	
4413	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4414	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4415	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%.
4416	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4417	SACCHARUM OFFICINARUM	A, E, H	
4418	SAFFLOWER OIL	A, E, H	
4419	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4420	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%.
4421	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%.
4422	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'
4423	SAGE OIL SPANISH	A, E, H	
4424	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%.
4425	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%.

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4426	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4427	SALIX ALBA	A, E, H	
4428	SALIX DAPHNOIDES	A, H	
4429	SALIX DISCOLOR	A, H	
4430	SALIX FRAGILIS	A, H	
4431	SALIX NIGRA	A, H	
4432	SALIX PURPUREA	A, H	
4433	SALSOLA KALI	A, H	
4434	SALVIA CHINENSIS	A, H	
4435	SALVIA FRUTICOSA	A, H	
4436	SALVIA HISPANICA	A, E, H	
4437	SALVIA LAVANDULAEFOLIA	A, H	
4438	SALVIA MILTIORRHIZA	A, H	
4439	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%.
4440	SALVIA SCLAREA	A, E, H	
4441	SAMBUCUS CANADENSIS	A, H	
4442	SAMBUCUS EBULUS	A, H	
4443	SAMBUCUS NIGRA	A, E, H	
4444	SANDALWOOD OIL EAST INDIAN	A, E, H	
4445	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4446	SANICULA EUROPAEA	A, H	
4447	SANTALUM ALBUM	A, E, H	
4448	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.
4449	SAPINDUS MUKOROSSI	A, H	
4450	SAPONARIA OFFICINALIS	A, H	
4451	SAPOSHNIKOVIA DIVARICATA	A, H	
4452	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%.
4453	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.
4454	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.
4455	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%.
4456	SATUREIA HORTENSIS	A, H	
4457	SATUREIA MONTANA	A, H	
4458	SAUROPUS SPATULIFOLIUS	A, H	
4459	SAURURUS CHINENSIS	A, H	
4460	SAUSSUREA COSTUS	A, H	
4461	SAVORY OIL SUMMER	A, H	
4462	SAXIFRAGA GRANULATA	A, E, H	
4463	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%.
4464	SCAPHIUM SCAPHIGERUM	A, H	
4465	SCHEFFLERA HEPTAPHYLLA	A, H	
4466	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4467	SCHINUS MOLLE	A, H	
4468	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%.
4469	SCHISANDRA CHINENSIS	A, E, H	
4470	SCHIZONEPETA TENUIFOLIA	A, E, H	
4471	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%.
4472	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%.
4473	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%.
4474	SCLERANTHUS ANNUUS	A, H	
4475	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4476	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%.
4477	SCROPHULARIA NINGPOENSIS	A, H	
4478	SCROPHULARIA NODOSA	A, H	
4479	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4480	SCUTELLARIA BAICALENSIS	A, E, H	
4481	SCUTELLARIA BARBATA	A, H	

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4482	SCUTELLARIA LATERIFLORA	A, E, H	
4483	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%.
4484	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%.
4485	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%.
4486	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.
4487	SEDUM ACRE	A, H	
4488	SELAGINELLA TAMARISCINA	A, H	
4489	SELENICEREUS GRANDIFLORUS	A, E, H	
4490	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.'
4491	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.'
4492	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.’
4493	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4494	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.
4495	SEMOLINA	E	
4496	SEMPERVIVUM TECTORUM	A, H	
4497	SENEGA ROOT DRY	A, H	
4498	SENEGA ROOT POWDER	A, H	
4499	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'.
4500	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

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		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 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'.
4502	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'.
4503	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'.
4504	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 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'.
4505	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'.
4506	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'; 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'.
4507	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'.
4508	SEPIA	H	Only for use as an active homoeopathic ingredient. The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (a) The following warning statement is required on the medicine label:

			- (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
4509	SEQUOIA SEMPERVIRENS	A, H	
4510	SEQUOIADENDRON GIGANTEUM	A, H	
4511	SERENOA REPENS	A, H	
4512	SERINE	A, E	
4513	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4514	SESAME OIL	A, E, H	
4515	SESAME SEED	E	
4516	SESAMUM INDICUM	A, E, H	
4517	SETARIA ITALICA	A, H	
4518	SHARK CALCIUM CHONDROITIN SULFATE	A	
4519	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)
4520	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%.
4521	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4522	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%.
4523	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.'
4524	SHEA BUTTER	E	
4525	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4526	SHELLAC	E	
4527	SHEPHERD'S PURSE HERB DRY	A, H	
4528	SHEPHERD'S PURSE HERB POWDER	A, H	
4529	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%.
4530	SIGESBECKIA ORIENTALIS	A, E, H	
4531	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%.
4532	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%.

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4533	SILICA SILYLATE	E	Only for use in topical medicines for dermal application.
4534	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4535	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4536	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).
4537	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).
4538	SILVER BEET	E, H	
4539	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%.
4540	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4541	SILYBUM MARIANUM	A, E, H	
4542	SIMABA CEDRON	A, H	
4543	SIMETHICONE	E	
4544	SIMMONDSIA CHINENSIS	A, E, H	
4545	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%.
4546	SINAPIS ARVENSIS	A, H	
4547	SINOMENIUM ACUTUM	A, H	
4548	SIPHONESTEGIA CHINENSIS	A, H	
4549	SIRAITIA GROSVENORII	A, E, H	
4550	SISYMBRIUM OFFICINALE	A, H	
4551	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4552	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.'
4553	SLIPPERY ELM BARK DRY	A, H	
4554	SLIPPERY ELM BARK POWDER	A, E, H	
4555	SMILAX ARISTOLOCHIIFOLIA	A, H	
4556	SMILAX CHINA	A, H	
4557	SMILAX GLABRA	A, H	
4558	SMILAX OFFICINALIS	A, E, H	
4559	SMILAX ORNATA	A, E, H	
4560	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%.
4561	SODIUM ACETATE	E	
4562	SODIUM ACETYLATED HYALURONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4563	SODIUM ACID CITRATE	A, E, H	When sodium acid citrate is used as an active ingredient, only for use in oral medicines.
4564	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%.

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4565	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).
4566	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).
4567	SODIUM ALGINATE	E	
4568	SODIUM ASCORBATE	A, E, H	
4569	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%.
4570	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%.
4571	SODIUM BENZOATE	E	
4572	SODIUM BETA-HYDROXY-	A, H	

	BETA-METHYLBUTYRATE		
4573	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4574	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.'
4575	SODIUM BISULFITE	E	
4576	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%.
4577	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'.
4578	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4579	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.
4580	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4581	SODIUM CARBONATE	E	
4582	SODIUM CARBONATE MONOHYDRATE	E	
4583	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%.
4584	SODIUM CARRAGEENAN	E	
4585	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%.
4586	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4587	SODIUM CHLORIDE	A, E, H	
4588	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).
4589	SODIUM CITRATE	A, E	When for use as an active ingredient, only for oral use.
4590	SODIUM CITRATE DIHYDRATE	A, E	When for use as an active ingredient, only for oral use.
4591	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%.
4592	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4593	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.

4594	SODIUM CYCLAMATE	E	
4595	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4596	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%.
4597	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4598	SODIUM ERYTHORBATE	E	
4599	SODIUM ETHYL HYDROXYBENZOATE	E	
4600	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

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			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.'
4601	SODIUM FUMARATE	E	
4602	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'.
4603	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4604	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.
4605	SODIUM HYDROXYCITRATE	A	
4606	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%.
4607	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4608	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of sodium hypochlorite. The concentration of chlorine in the medicine must not be more than 4%.
4609	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal

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			application.
4610	SODIUM LACTATE	E	
4611	SODIUM LAURETH SULFATE	E	
4612	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%.
4613	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%.
4614	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4615	SODIUM LAURYL PHOSPHATE	E	
4616	SODIUM LAURYL SULFATE	E	
4617	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4618	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4619	SODIUM MANNOSE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.

4620	SODIUM METABISULFITE	E	
4621	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%.
4622	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine must be no more than 2%.
4623	SODIUM METHYL HYDROXYBENZOATE	E	
4624	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.
4625	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:

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			(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.'
4626	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%.
4627	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4628	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4629	SODIUM PANTOTHENATE	A, E, H	
4630	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4631	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).
4632	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.
4633	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4634	SODIUM POLYACRYLATE STARCH	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 1%.
4635	SODIUM POLYMETAPHOSPHATE	E	
4636	SODIUM PROPIONATE	E	
4637	SODIUM PROPYL HYDROXYBENZOATE	E	
4638	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%.
4639	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.'
4640	SODIUM SELENATE DECAHYDRATE	A	Selenium is a mandatory component of sodium selenate decahydrate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4641	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.'
4642	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.'
4643	SODIUM SILICATE	E	
4644	SODIUM STARCH GLYCOLLATE	E	
4645	SODIUM STARCH GLYCOLLATE TYPE A	E	
4646	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4647	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%.
4648	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%.
4649	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4650	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%.
4651	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4652	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'.
4653	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'.
4654	SODIUM SULFITE	E	
4655	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application.
4656	SODIUM TRIPOLYPHOSPHATE	E	Only for use when the route of administration is topical for dermal application, mucous membrane (buccal mucosa) or dental. Not to be included in topical medicines intended for use in the eye.

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			The concentration in the medicine must be no more than 5%.
4657	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.
4658	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.
4659	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%.
4660	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.

4661	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.
4662	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.
4663	SOLIDAGO GIGANTEA	A, H	
4664	SOLIDAGO GIGANTEA MIS	A, E, H	
4665	SOLIDAGO VIRGAUREA	A, E, H	
4666	SOLUBLE MAIZE STARCH	E	
4667	SOLUBLE POTATO STARCH	E	
4668	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4669	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4670	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4671	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%.
4672	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.

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4673	SOPHORA FLAVESCENS	A, E, H	
4674	SOPHORA TONKINENSIS	A, H	
4675	SORBIC ACID	E	
4676	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4677	SORBITAN MONO-OLEATE	E	
4678	SORBITAN MONOLAURATE	E	
4679	SORBITAN MONOSTEARATE	E	
4680	SORBITAN OLEATE	E	
4681	SORBITAN OLIVATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
4682	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%.
4683	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4684	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4685	SORBITAN STEARATE	E	
4686	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4687	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.
4688	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.
4689	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.
4690	SORBUS AUCUPARIA	A, H	
4691	SORGHUM	E	
4692	SORGHUM VULGARE	A, H	
4693	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid. The concentration of soy

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			phosphatidylserine in the medicine must be no more than 15%.
4694	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%.
4695	SOY POLYSACCHARIDE	E	
4696	SOY PROTEIN	E	
4697	SOY STEROL	E	
4698	SOYA BEAN	E	
4699	SOYA BRAN	E	
4700	SOYA OIL	A, E, H	
4701	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%.
4702	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%.
4703	SPARGANIUM STOLONIFERUM	A, H	
4704	SPARTIUM JUNCEUM	A, H	
4705	SPATHOLOBUS SUBERECTUS	A, H	
4706	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.
4707	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

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		flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. 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 use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4708	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%.
4709	SPIGELIA ANTHELMIA	A, H	
4710	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4711	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.
4712	SPINACH	E	
4713	SPINACIA OLERACEA	A, E, H	
4714	SPIRODELA POLYRRHIZA	A, H	
4715	SPIRULINA	E	
4716	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use as an excipient for oral routes of administration.

4717	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use as an excipient for oral routes of administration.
4718	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%.
4719	SQUALANE	E	Only for use in topical medicines for dermal application.
4720	SQUALENE	A, E	
4721	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 requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2022; and - released for supply before 1 March 2023. (a) The medicine requires one of the following warning statements on the medicine label: - (SFOOD) 'Derived from seafood'; or - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’. The requirement specified in

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			paragraph (b) below applies to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (b) The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
4722	SQUILL DRY	A, H	
4723	SQUILL INDIAN DRY	A, H	
4724	SQUILL INDIAN POWDER	A, H	
4725	SQUILL POWDER	A, H	
4726	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.'
4727	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.'
4728	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.'
4729	STACHYS OFFICINALIS	A, E, H	
4730	STACHYS PALUSTRIS	A, H	
4731	STACHYURUS HIMALAICUS	A, H	
4732	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%.
4733	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4734	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).
4735	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%.
4736	STARCH SODIUM OCTENYL SUCCINATE	E	
4737	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.

4738	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4739	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4740	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4741	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4742	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).
4743	STEARETH-10	E	Only for use in topical medicines for dermal application.
4744	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%.
4745	STEARETH-2	E	Only for use in topical medicines for dermal

			application.
4746	STEARETH-20	E	Only for use in topical medicines for dermal application.
4747	STEARETH-21	E	Only for use in topical medicines for dermal application.
4748	STEARETH-5	E	Only for use in topical medicines for dermal application.
4749	STEARIC ACID	E	
4750	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%.
4751	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%.
4752	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4753	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4754	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.

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4755	STEARYL ALCOHOL	E	
4756	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.
4757	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).
4758	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4759	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4760	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%.
4761	STEARYL STEARATE	E	Only for use in topical medicines for dermal

			application.
4762	STELLARIA CHAMAEJASME	A, H	
4763	STELLARIA DICHOTOMA	A, H	
4764	STELLARIA MEDIA	A, E, H	
4765	STEMONA JAPONICA	A, H	
4766	STEMONA SESSILIFOLIA	A, H	
4767	STENOTAPHRUM SECUNDATUM	A, H	
4768	STEPHANIA TETRANDA	A, H	
4769	STERCULIA	A, H	
4770	STERCULIA TRAGACANTHA	A, H	
4771	STERCULIA URENS	A, H	
4772	STEVIA REBAUDIANA	A, E, H	
4773	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4774	STILLINGIA SYLVATICA	A, H	
4775	STORAX PREPARED	A, E, H	
4776	STRAWBERRY	E	
4777	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%.
4778	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'.

4779	STREPTOCOCCUS THERMOPHILUS	A	
4780	STROBILANTHES CUSIA	A, H	
4781	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%.
4782	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4783	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4784	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4785	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%.
4786	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%.
4787	STYPHNOLOBIUM JAPONICUM	A, E, H	
4788	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%.
4789	STYRAX BENZOIN	A, E, H	
4790	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%.
4791	STYRAX PARALLELONEURUM	A, H	
4792	STYRAX TONKINENSIS	A, H	
4793	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%.
4794	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4795	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%.
4796	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4797	SUCCINIC ACID	E	
4798	SUCRALOSE	E	
4799	SUCROSE	E	
4800	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%.
4801	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%.
4802	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%.
4803	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4804	SUCROSE LAURATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate.
4805	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory

			component of sucrose octaacetate.
4806	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4807	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).
4808	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.
4809	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%.

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4810	SUDAN III	E	Permitted for use only as a colour for topical use.
4811	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).
4812	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of sugarcane.
4813	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4814	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%.
4815	SULFUR DIOXIDE	E	
4816	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4817	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%.
4818	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%.
4819	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).
4820	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).
4821	SUNFLOWER OIL	A, E, H	

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4822	SUNFLOWER SEED	E, H	
4823	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4824	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
4825	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4826	SWEDE	E	
4827	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%.
4828	SWEET POTATO	E	
4829	SWERTIA CHIRATA	A, H	
4830	SWIETENIA MAHOGANI	A, H	
4831	SYAGRUS ROMANZOFFIANA	A, E, H	
4832	SYMPHYOTRICHUM NOVI-BELGII	A, H	
4833	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%.

4834	SYMPLOCARPUS FOETIDUS	A, H	
4835	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4836	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.
4837	SYNTHETIC WAX	E	
4838	SYRINGA RETICULATA	A, H	
4839	SYRINGA VULGARIS	A, H	
4840	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. When the plant preparation is oil or distillate, the concentration of oil or distillate in the product is greater than

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			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%.
4841	SYZYGIUM CUMINI	A, H	
4842	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%.
4843	TABEBUIA SERRATIFOLIA	A, E, H	
4844	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%.
4845	TAGETES MINUTA	A, E, H	
4846	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%.
4847	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4848	TALLOW	E	Only for use in topical medicines for dermal application.
4849	TALLOW GLYCERIDES	E	
4850	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%.
4851	TAMARIX APHYLLA	A, H	
4852	TAMARIX CHINENSIS	A, H	
4853	TAMARIX GALLICA	A, H	
4854	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.
4855	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4856	TANACETUM PARTHENIUM	A, E, H	
4857	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%.

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4858	TANGERINE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4859	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.
4860	TANNIC ACID	E	
4861	TAPIOCA STARCH	E	
4862	TARAXACUM MONGOLICUM	A, E, H	
4863	TARAXACUM OFFICINALE	A, E, H	
4864	TARO	E	
4865	TARRAGON OIL	A, E, H	
4866	TARTARIC ACID	E	
4867	TARTRAZINE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4868	TARTRAZINE ALUMINIUM LAKE	E	Only for use as a colour. Only for use in medicines for topical and oral administration.
4869	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%.

4870	TAURINE	A, E	
4871	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4872	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'.
4873	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4874	TERMINALIA CATAPPA	A, H	
4875	TERMINALIA CHEBULA	A, H	
4876	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%.
4877	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%.
4878	TERPENE RESIN	E	Terpene resin must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application.
4879	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%.
4880	TERPINEOL	E	
4881	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%.
4882	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%.
4883	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%.
4884	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%.
4885	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%.
4886	TERT-BUTYL ALCOHOL	E	Only for use in topical

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			medicines for dermal application.
4887	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%.
4888	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%.
4889	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%.
4890	TETRACLINIS ARTICULATA	A, E, H	
4891	TETRADECYL AMINOBUTYROYLVALYLAMINOBUTYRIC UREA TRIFLUOROACETATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
4892	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.
4893	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%.
4894	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%.
4895	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%.
4896	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%.
4897	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%.
4898	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%.
4899	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%.
4900	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%.
4901	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%.
4902	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%.
4903	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4904	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%.
4905	TETRAPANAX PAPYRIFER	A, H	
4906	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4907	TETRASODIUM PYROPHOSPHATE	E	
4908	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4909	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4910	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.
4911	THAPSIA GARGANICA	A, H	

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4912	THAUMATIN	E	
4913	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%.
4914	THEMEDA TRIANDRA	A, H	
4915	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).
4916	THEOBROMA OIL	A, E, H	
4917	THIAMINE	A, E	
4918	THIAMINE HYDROCHLORIDE	A, E	
4919	THIAMINE NITRATE	A, E	
4920	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

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			medicine must be no more than 1%.
4921	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%.
4922	THLASPI ARVENSE	A, E, H	
4923	THREONINE	A, E	
4924	THUJA OCCIDENTALIS	A, H	
4925	THUJA PLICATA	A, E, H	
4926	THYME HERB DRY	A, E, H	
4927	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).
4928	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.
4929	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.
4930	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).
4931	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4932	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).
4933	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).
4934	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).
4935	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).
4936	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).
4937	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4938	TILACTASE	A	Must be derived from Aspergillus oryzae and comply with the relevant USP monograph.
4939	TILIA CORDATA	A, E, H	
4940	TILIA PLATYPHYLLOS	A, E, H	
4941	TILIA TOMENTOSA	A, H	
4942	TILIA X VULGARIS	A, E, H	
4943	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%.
4944	TIN	H	Only for use as an active homoeopathic ingredient.
4945	TINOSPORA CORDIFOLIA	A, H	
4946	TINOSPORA SINENSIS	A, H	
4947	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

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			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).
4948	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%.
4949	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%
4950	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%.
4951	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%
4952	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4953	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%.
4954	TOLU BALSAM	A, E, H	
4955	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%.
4956	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

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			fragrance concentration in a medicine must be no more 1%.
4957	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%.
4958	TOMATO	E	
4959	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%.
4960	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%.
4961	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%.
4962	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.

4963	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.
4964	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4965	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4966	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4967	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%.
4968	TRAGACANTH	A, E	
4969	TRAMETES VERSICOLOR	A, H	
4970	TRAMETES VERSICOLOR PROTEOGLYCAN	A, H	Only for use in oral medicines.

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	CONCENTRATE		
4971	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%.
4972	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.
4973	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%.
4974	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%.
4975	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%.
4976	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%.
4977	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%.
4978	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%.
4979	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4980	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%.
4981	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%.
4982	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%.
4983	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.
4984	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%.
4985	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%.
4986	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%.
4987	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%.
4988	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%.
4989	TRANS-METHYL-2-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4990	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of treacle.
4991	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%.
4992	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.

4993	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.
4994	TREMELLA FUCIFORMIS	A, H	
4995	TRIACETIN	E	
4996	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4997	TRIADICA SEBIFERA	A, H	
4998	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.
4999	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.
5000	TRIBEHENIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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			The concentration in the medicine must be no more than 6%.
5001	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%.
5002	TRIBULUS TERRESTRIS	A, E, H	
5003	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%.
5004	TRICALCIUM PHOSPHATE	E	
5005	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%.
5006	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%.
5007	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.

5008	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%.
5009	TRICHODERMA VIRIDE	A, E, H	
5010	TRICHOSANTHES KIRILOWII	A, E, H	
5011	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
5012	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%.
5013	TRIDECANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5014	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
5015	TRIDECETH-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.

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5016	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%.
5017	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
5018	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%.
5019	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%.
5020	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
5021	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
5022	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%.
5023	TRIETHYL CITRATE	E	
5024	TRIETHYLENE GLYCOL	E	
5025	TRIFOLIUM PRATENSE	A, E, H	
5026	TRIFOLIUM REPENS	A, H	
5027	TRIGONELLA FOENUM-GRAECUM	A, E, H	
5028	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%.
5029	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
5030	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
5031	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%.
5032	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

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			5%.
5033	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
5034	TRILAURIN	E	Only for use in topical medicines for dermal application.
5035	TRILISA ODORATISSIMA	A, H	
5036	TRILLIUM ERECTUM	A, H	
5037	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%.
5038	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%.
5039	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%.
5040	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%.
5041	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%.
5042	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%.
5043	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5044	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%.
5045	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5046	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%.
5047	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%.
5048	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%.
5049	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%.
5050	TRIOSTEUM PERFOLIATUM	A, H	
5051	TRIOXAUNDECANEDIOIC ACID	E	
5052	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%.
5053	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%.

5054	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).
5055	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%.
5056	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
5057	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%.
5058	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%.
5059	TRISTEARIN	E	
5060	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.
5061	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.
5062	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%.
5063	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5064	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
5065	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).
5066	TROLLIUS CHINENSIS	A, H	
5067	TROMETAMOL	E	
5068	TROMETAMOL HYDROCHLORIDE	E	
5069	TROPAEOLUM MAJUS	A, E, H	
5070	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5071	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%.
5072	TSUGA CANADENSIS	A, H	
5073	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%.
5074	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5075	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%.
5076	TURNIP	E	
5077	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than 25%.
5078	TYPHA ANGUSTIFOLIA	A, H	
5079	TYPHA LATIFOLIA	A, H	
5080	TYPHONIUM GIGANTEUM	A, H	
5081	TYROSINE	A, E	