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

(section 4)

Part 2 – Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3598	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%.
3599	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%.
3600	PADIMATE O	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			intended for use in the eye. The concentration in the medicine must be no more than 8%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (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).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3601	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%.
3602	PAEONIA LACTIFLORA	A, E, H	
3603	PAEONIA OBOVATA	A, H	
3604	PAEONIA SUFFRUTICOSA	A, E, H	
3605	PAEONIA VEITCHII	A, H	
3606	PALIURUS SPINA-CHRISTI	A, H	
3607	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3608	PALM FRUIT OIL	A, E, H	
3609	PALM GLYCERIDES	E	
3610	PALM KERNEL OIL	A, E, H	
3611	PALM TOCOTRIENOLS COMPLEX	A, H	
3612	PALMARIA PALMATA	A, H	
3613	PALMAROSA OIL	A, E, H	
3614	PALMITIC ACID	E	

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
3615	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3616	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%.
3617	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%
3618	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%.
3619	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 0.0005%.
3620	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%.
3621	PANAX GINSENG	A, E, H	
3622	PANAX JAPONICUS	A, H	
3623	PANAX NOTOGINSENG	A, H	
3624	PANAX PSEUDOGINSENG	A, H	
3625	PANAX QUINQUEFOLIUS	A, H	
3626	PANICUM MILIACEUM	A, H	
3627	PANTETHINE	E	Only for use in topical medicines for dermal application.
3628	PANTHENOL	A, E	
3629	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3630	PANTOLACTONE	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3631	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3632	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%.
3633	PAPAIN	A, E	
3634	PAPER	E	Only for use in topical medicines for dermal application.
3635	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%.
3636	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3637	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%.
3638	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%.
3639	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			medicine must be no more than 1%.
3640	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%.
3641	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%.
3642	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

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
			must be no more than 5%.
3643	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%.
3644	PARA-HYDROXYBENZOIC ACID	E	
3645	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%.
3646	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3647	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%.
3648	PARA-METHYL DIMETHYLBENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3649	PARA-PROPYL 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3650	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%.
3651	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%.
3652	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%.
3653	PARA-TOLYL ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3654	PARAMERIA LAEVIGATA	A, H	
3655	PARIETARIA JUDAICA	A, H	
3656	PARIS POLYPHYLLA	A, H	
3657	PARIS QUADRIFOLIA	A, H	
3658	PARSLEY	E, H	
3659	PARSLEY HERB DRY	A, E, H	
3660	PARSLEY HERB OIL	A, E, H	
3661	PARSLEY HERB POWDER	A, E, H	
3662	PARSLEY SEED OIL	A, E, H	
3663	PARTHENOCISSUS TRICUSPIDATA	A, H	
3664	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3665	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%.
3666	PASPALUM NOTATUM	A, H	
3667	PASSIFLORA CAERULEA	A, H	
3668	PASSIFLORA EDULIS	E	
3669	PASSIFLORA HERB DRY	A, H	
3670	PASSIFLORA INCARNATA	A, E, H	
3671	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%.
3672	PATENT BLUE V	E	Permitted for use only as a colour for oral and topical use.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
3673	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
3674	PATRINIA SCABIOSIFOLIA	A, H	
3675	PATRINIA VILLOSA	A, H	
3676	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana when used for oral ingestion. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
3677	PAULLINIA PINNATA	A, H	
3678	PAWPAW	E	
3679	PEA	E	
3680	PEA STARCH	E	
3681	PEACH	E	
3682	PEANUT	E	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains Peanut' (or words to that effect).
3683	PEAR	E	
3684	PECAN	E	
3685	PECTIN	A, E	
3686	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%.
3687	PEG-10 SOYA STEROL	E	Only for use in topical medicines

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for dermal application.
3688	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3689	PEG-12 DILAURATE	E	
3690	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%.
3691	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3692	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3693	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3694	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3695	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%.
3696	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3697	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3698	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3699	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3700	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 be no more than 10%. When used in primary sunscreen products and listed in the Register

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (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).
3701	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3702	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3703	PEG-35 CASTOR OIL	E	
3704	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3705	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%.
3706	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3707	PEG-40 CASTOR OIL	E	
3708	PEG-40 HYDROGENATED CASTOR OIL	E	
3709	PEG-40 SORBITAN DIISOSTEARATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3710	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3711	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3712	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3713	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3714	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.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
			The concentration in the medicine must be no more than 0.6%.
3715	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3716	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%.
3717	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%.
3718	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3719	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3720	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3721	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3722	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3723	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%.
3724	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3725	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%.
3726	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3727	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.
3728	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3729	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3730	PEG-9 POLYDIMETHYLSILOXYETHYL	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	DIMETICONE		included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.5%.
3731	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%.
3732	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%.
3733	PELARGONIUM GRAVEOLENS	A, E, H	
3734	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3735	PELTIGERA CANINA	A, H	
3736	PENICILLIUM EXPANSUM	A, H	
3737	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.
3738	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 0.018%
3739	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%.
3740	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3741	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%.
3742	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3743	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%.
3744	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%.
3745	PEPPER BLACK	E, H	
3746	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3747	PEPPER WHITE	E, H	
3748	PEPPERMINT AMERICAN EXT.	E	Menthol is a mandatory component of peppermint american ext. When the medicine is for topical use: a) the medicine must not be intended for use in the eye or on damaged skin; b) the maximum concentration of menthol must not exceed 5%; and c) 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; and - (EYE) Avoid contact with eyes (or words to that effect). When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3749	PEPPERMINT LEAF DRY	A, E, H	When the ingredient is included in a medicine that is listed in the Register:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of peppermint leaf dry. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) 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; and - (EYE) Avoid contact with eyes

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			(or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3750	PEPPERMINT LEAF POWDER	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of peppermint leaf powder. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			menthol must not exceed 5%; and (iii) 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; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3751	PEPPERMINT OIL	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018, and supplied on or after 1 January 2020 the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			requirements under (a)-(c). a) Menthol is a mandatory component of peppermint oil. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) 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; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3752	PEPPERMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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: a) the medicine must not be intended for use in the eye or on damaged skin; b) the maximum concentration of menthol must not exceed 5%; and c) 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; and - (EYE) Avoid contact with eyes (or words to that effect). When the medicine is for internal use, the maximum recommended

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
			daily dose must not contain more than 1 gram of menthol.
3753	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: a) the medicine must not be intended for use in the eye or on damaged skin; b) the maximum concentration of menthol must not exceed 5%; and c) 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; and - (EYE) Avoid contact with eyes

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			(or words to that effect). When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3754	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3755	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%.
3756	PERILLA FRUTESCENS	A, E, H	Rosmarinic acid and vicenin-2 are only permitted for use if the plant part of Perilla frutescens is leaf.
3757	PERILLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3758	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%.
3759	PERMETHRIN	E	The concentration of in the medicine must be no more than 2%.
3760	PERSEA AMERICANA	A, E, H	
3761	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%.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
3762	PERSICARIA CHINENSIS	A, H	
3763	PERSICARIA TINCTORIA	A, H	
3764	PERSIMMON	E	
3765	PERU BALSAM	A, E, H	
3766	PERU BALSAM OIL	A, E, H	
3767	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%
3768	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3769	PETITGRAIN OIL CITRONNIER	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. When included in a medicine for use on the lips the concentration of petitgrain oil citronnier must be no more than 0.1%. When included in dermal creams for infant use the concentration of petitgrain oil citronnier must be no more than 0.5% The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3770	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.
3771	PETITGRAIN OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			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%.
3772	PETROSELINUM CRISPUM	A, E, H	
3773	PEUCEDANUM PRAERUPTORUM	A, E, H	
3774	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).
3775	PHALARIS ARUNDINACEA	A, H	
3776	PHALARIS CANARIENSIS	A, H	
3777	PHASEOLUS COCCINEUS	A, H	
3778	PHASEOLUS VULGARIS	A, H	
3779	PHELLINUS ROBINIAE	A, E, H	
3780	PHELLODENDRON AMURENSE	A, E, H	
3781	PHELLODENDRON CHINENSE	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3782	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3783	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%.
3784	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%.
3785	PHENETHYL ALCOHOL	E	Permitted for use only:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			a) in topical medicines for dermal application; and b) for internal use in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation concentration in a medicine must be no more than 5%.
3786	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%.
3787	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%
3788	PHENETHYL ISOAMYL ETHER	E	Permitted for use only in combination with other permitted

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3789	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%.
3790	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%.
3791	PHENETHYL PHENYLACETATE	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients 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%.
3792	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%.
3793	PHENOL	E	Only for use in topical medicines for dermal application. The concentration of phenol in the medicine must be no more than 1%.
3794	PHENOXYACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3795	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The concentration of phenoxyethanol in the preparation must not exceed 15%.
3796	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%.
3797	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
3798	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3799	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3800	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%.
3801	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%.
3802	PHENYLACETALDEHYDE GLYCERYLACETAL	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3803	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%.
3804	PHENYLALANINE	A, E	When for oral ingestion the medicine requires the following warning statement on the medicine label: - (PKU) 'Phenylketonurics are warned that this medicine contains phenylalanine' (or words to that effect). When the medicine contains more than 500mg in the maximum recommended daily dose it requires the following warning statement on the medicine label: - (PREGNT2) 'Do not use if

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			pregnant or likely to become pregnant'.
3805	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 be no more than 4%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3806	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%.
3807	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%.
3808	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			medicine must be no more 1%.
3809	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%.
3810	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%.
3811	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3812	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%.
3813	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%.
3814	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%.
3815	PHENYLPROPANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 0.16%.
3816	PHLEUM PRATENSE	A, H	
3817	PHLOXINE B	E	Permitted for use only as a colour for oral and topical use.
3818	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
3819	PHOENIX DACTYLIFERA	A, E, H	
3820	PHOSPHATIDYL CHOLINE	E	
3821	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%.
3822	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3823	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3824	PHOTINIA SERRULATA	A, H	
3825	PHRAGMITES AUSTRALIS	A, H	
3826	PHYLLANTHUS AMARUS	A, H	
3827	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application. When ascorbic acid is claimed as a component the plant part is restricted to fruit.
3828	PHYLLOSTACHYS NIGRA	A, E, H	
3829	PHYSALIS ALKEKENGI	A, H	
3830	PHYSALIS PUBESCENS	A, H	
3831	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
3832	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3833	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3834	PHYTOMENADIONE	A, E	
3835	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%.
3836	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%.
3837	PICEA ABIES	A, H	
3838	PICEA MARIANA	A, H	
3839	PICRASMA EXCELSA	A, E, H	
3840	PICRORRHIZA KURROA	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3841	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%.
3842	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%.
3843	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%.
3844	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3845	PIGMENT RED 53	E	Permitted for use only as a colour

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
			for topical use.
3846	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3847	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3848	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.
3849	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3850	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3851	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3852	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%.
3853	PILOCARPUS MICROPHYLLUS	A, H	Pilocarpine is a mandatory component of Pilocarpus microphyllus. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3854	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%.
3855	PIMENTA FRUIT OIL	A, E, H	
3856	PIMENTA LEAF OIL	A, E, H	
3857	PIMENTA OFFICINALIS	A, E, H	
3858	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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'.
3859	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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).
3860	PIMPINELLA SAXIFRAGA	A, E, H	
3861	PINE NEEDLE OIL SCOTCH	A, E, H	
3862	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%.
3863	PINE OIL AROMATIC	A, E, H	
3864	PINE OIL PUMILIO	A, E, H	
3865	PINEAPPLE	E	
3866	PINEAPPLE OILS	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3867	PINELLIA TERNATA	A, H	
3868	PINUS CONTORTA	A, E, H	
3869	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%.
3870	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%.
3871	PINUS MONTICOLA	A, E, H	
3872	PINUS MUGO	A, E, H	
3873	PINUS PALUSTRIS	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3874	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%.
3875	PINUS PONDEROSA	A, E, H	
3876	PINUS RADIATA	A, E, H	
3877	PINUS STROBUS	A, E, H	
3878	PINUS SYLVESTRIS	A, E, H	
3879	PINUS TABULIFORMIS	A, E, H	
3880	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%.
3881	PIPENZOLATE BROMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3882	PIPER CHABA	A, E, H	
3883	PIPER CUBEBA	A, E, H	
3884	PIPER KADSURA	A, E, H	
3885	PIPER LONGUM	A, E, H	
3886	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:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (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.
3887	PIPER NIGRUM	A, E, H	
3888	PIPER SARMENTOSUM	A, E, H	
3889	PIPERIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3890	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%.
3891	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%.
3892	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3893	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%.
3894	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (PIPBUT) 'Contains piperonyl butoxide' (or words to that effect).
3895	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.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			The concentration in the medicine must be no more than 1% in wash-on/wash-off medicines and 0.5% in leave-on medicines.
3896	PISCIDIA PISCIPULA	A, E, H	
3897	PISTACIA LENTISCUS	A, E, H	
3898	PISUM SATIVUM	A, E, H	
3899	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3900	PLANTAGO AFRA	A, E, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3901	PLANTAGO ARENARIA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3902	PLANTAGO ASIATICA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3903	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 medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3904	PLANTAGO MAJOR	A, E, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3905	PLANTAGO OVATA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3906	PLANTAGO SEED DRY	A, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3907	PLATANUS OCCIDENTALIS	A, E, H	
3908	PLATANUS RACEMOSA	A, H	
3909	PLATANUS X ACERIFOLIA	A, H	
3910	PLATYCODON GRANDIFLORUS	A, E, H	
3911	PLECTRANTHUS BARBATUS	A, E, H	
3912	PLICATONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3913	PLUM	E	
3914	PLUMBAGO EUROPAEA	A, H	
3915	PLUMERIA ALBA	A, E, H	
3916	PLUMERIA RUBRA	A, E, H	
3917	POA NEMORALIS	A, H	
3918	POA PRATENSIS	A, H	
3919	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%.
3920	POGOSTEMON CABLIN	A, E, H	
3921	POLACRILIN	E	
3922	POLACRILIN POTASSIUM	E	
3923	POLAPREZINC	A	Only for use in oral medicines. Zinc is a mandatory component of Polaprezinc. The maximum recommended daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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).
3924	POLIGLUSAM	A, E	When for internal use, the following warning statements are required on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect); and - (SFOOD) 'Derived from seafood'. When for internal use and the dosage form is a powdered

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			preparation, the medicine requires the following warning statements on the medicine label: - (DNTPOW) 'Do not take powder alone. Mix with food or fluid'. When used as an excipient, only for use in topical medicines for dermal application. In addition, when the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a) & (b). a) The average molecular mass of poliglusam must be greater than 2 kilodaltons. b) When for internal use, the medicine must not contain more than 1750 milligrams of poliglusam per maximum recommended daily dose.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3925	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	When for oral use, the medicine must provide no more than 2000 milligrams of Poliglusam derived from Aspergillus niger per maximum recommended daily dose and requires the following warning statement 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). If the medicine is a powdered dosage form, the medicine also requires the following warning statement on the medicine label: - '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.
3926	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
3927	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).
3928	POLOXAMER	E	Only for use in topical medicines for dermal application.
3929	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%.
3930	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 1%.
3931	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%.
3932	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%.
3933	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%.
3934	POLYACRYLATE-1 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.4%.
3935	POLYACRYLIC ACID	E	
3936	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3937	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%.
3938	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3939	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%.
3940	POLYCAPROLACTONE	E	Only for use in topical medicines

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for dermal 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%.
3941	POLYDECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3942	POLYDEXTROSE	E	
3943	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%.
3944	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%

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
3945	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%.
3946	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%.
3947	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%.
3948	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3949	POLYETHYLENE	E	
3950	POLYGALA CHINENSIS	A, H	
3951	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.
3952	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
3953	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
3954	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%.
3955	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 3.0%.
3956	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3957	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. The concentration in the medicine must be no more than 3%.
3958	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3959	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%.
3960	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3961	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%.
3962	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%.
3963	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%.
3964	POLYGLYCERYL-3 POLYRICINOLEATE	E	
3965	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIMER DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 5%.
3966	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%.
3967	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%.
3968	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
3969	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3970	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
3971	POLYGONATUM MULTIFLORUM	A, H	
3972	POLYGONATUM OFFICINALE	A, H	
3973	POLYGONATUM SIBIRICUM	A, E, H	
3974	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%.
3975	POLYGONUM BISTORTA	A, H	
3976	POLYGONUM ODORATUM	A, H	
3977	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
3978	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
3979	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
3980	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%.
3981	POLYMETHACRYLIC ACID	E	
3982	POLYMETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
3983	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 3%.
3984	POLYPORUS UMBELLATUS	A, H	
3985	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
3986	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%.
3987	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
3988	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3989	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%.
3990	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
3991	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
3992	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%.
3993	POLYQUATERNIUM-44	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
3994	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%.
3995	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
3996	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%
3997	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%.
3998	POLYSILICONE-15	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			intended for use in the eye. The concentration in the medicine must be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (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).
3999	POLYSILICONE-2	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.13%.
4000	POLYSORBATE 20	E	
4001	POLYSORBATE 40	E	
4002	POLYSORBATE 60	E	
4003	POLYSORBATE 65	E	
4004	POLYSORBATE 80	E	
4005	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4006	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%.
4007	POLYURETHANE-34	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% in spray

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			applications and 6% in non-spray applications.
4008	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%.
4009	POLYVINYL ACETATE	E	Only for use when the dosage form is chewing gum.
4010	POLYVINYL ACETATE PHTHALATE	E	
4011	POLYVINYL ALCOHOL	E	
4012	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4013	POMEGRANATE	E	
4014	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4015	PONCIRUS TRIFOLIATA	A, H	When used internally, oxedrine is a mandatory component of Poncirus

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			trifoliata. The quantity of Oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4016	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%.
4017	POPPY SEED	E, H	
4018	POPPY SEED OIL	E, H	
4019	POPULUS ALBA	A, H	
4020	POPULUS BALSAMIIFERA	A, E, H	
4021	POPULUS CANDICANS	A, H	
4022	POPULUS DELTOIDES	A, H	
4023	POPULUS NIGRA	A, H	
4024	POPULUS TREMULA	A, H	
4025	POPULUS TREMULOIDES	A, H	
4026	PORCINE	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4027	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%.
4028	PORTULACA OLERACEA	A, E, H	
4029	POTABLE WATER	E	
4030	POTASSIUM ACETATE	E	
4031	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4032	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4033	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4034	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
4035	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.
4036	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.
4037	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4038	POTASSIUM BICARBONATE	E	
4039	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4040	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.
4041	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4042	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: - (POTAS) 'Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			c) other than when used for oral rehydration therapy, the concentration must be no more than 550 mg per dosage unit. Medicines for use as oral rehydration therapy, are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and c) the medicine requires the warning statements: - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration in the medicine must

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			be no more than 3.75%.
4043	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.
4044	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%.
4045	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%.
4046	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4047	POTASSIUM GLUCONATE	A, E, H	When used as an active ingredient

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium gluconate.
4048	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.
4049	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.
4050	POTASSIUM HYDROXYCITRATE	A, H	
4051	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
4052	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%.
4053	POTASSIUM METABISULFITE	E	Permitted for use only in combination with other permitted

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4054	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%.
4055	POTASSIUM NITRATE	A, H	Only for dental use. The concentration in the medicine must be no more than 5%.
4056	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.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
4057	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%.
4058	POTASSIUM SORBATE	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4059	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4060	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4061	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.
4062	POTATO STARCH	E	
4063	POTENTILLA ANSERINA	A, H	
4064	POTENTILLA CHINENSIS	A, H	
4065	POTENTILLA DISCOLOR	A, H	
4066	POTENTILLA ERECTA	A, E, H	
4067	POTENTILLA REPTANS	A, H	
4068	POTERIUM OFFICINALE	A, E, H	
4069	POTERIUM SANGUISORBA	A, H	
4070	POVIDONE	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4071	POWDERED CELLULOSE	E	
4072	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%.
4073	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%.
4074	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%.
4075	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 1.4%.
4076	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%.
4077	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4078	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%.
4079	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4080	PPG-20 METHYL GLUCOSE ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			use in the eye. The concentration in the medicine must be no more than 0.5%.
4081	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4082	PPG-3 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4083	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4084	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4085	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4086	PRALINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4087	PREGELATINISED MAIZE STARCH	E	
4088	PREGELATINISED POTATO STARCH	E	
4089	PREGELATINISED RICE STARCH	E	
4090	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4091	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4092	PRICKLY ASH BARK DRY	A, H	
4093	PRICKLY ASH BARK POWDER	A, H	
4094	PRIMULA VERIS	A, E, H	
4095	PRIMULA VULGARIS	A, E, H	
4096	PRINSEPIA UNIFLORA	A, H	
4097	PROBOSCIDEA PARVIFLORA	A, H	
4098	PROGESTERONE	H	Only for use as an active homoeopathic ingredient.
4099	PROLINE	A, E	
4100	PROPAN-1-OL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 18%.
4101	PROPANE	E	Only for use as an excipient propellant ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4102	PROPANEDIOL	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%.
4103	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%.
4104	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4105	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%.
4106	PROPIONYLLEVOCARNITINE HYDROCHLORIDE	A, H	
4107	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			or swelling of the mouth or throat occurs, discontinue use.'
4108	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.'
4109	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'
4110	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4111	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.'
4112	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'
4113	PROPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4114	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4115	PROPYL GALLATE	E	
4116	PROPYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4117	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4118	PROPYLENE GLYCOL	E	
4119	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4120	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%.
4121	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%.
4122	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4123	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4124	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4125	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 1%.
4126	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4127	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4128	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4129	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4130	PROSOPIS JULIFLORA	A, H	
4131	PROTEASE	A	Must be derived from Aspergillus oryzae or Aspergillus niger. When the dosage form is undivided, the units 'haemoglobin unit on the tyrosine basis per gram' and 'Thousand haemoglobin units on the tyrosine basis per gram' are permitted. When the dosage form is divided, the units 'haemoglobin units on the tyrosine basis' and 'thousand

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			haemoglobin units on the tyrosine basis' are permitted.
4132	PROTEIN HYDROLYSATE	E	
4133	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%.
4134	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%.
4135	PRUNELLA VULGARIS	A, H	
4136	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			microgram/L or 0.0000001%.
4137	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%.
4138	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%.
4139	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4140	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%.
4141	PRUNUS DOMESTICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4142	PRUNUS DULCIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus dulcis when the plant part is seed.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			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%.
4143	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%.
4144	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			microgram/L or 0.0000001%.
4145	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%.
4146	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%.
4147	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4148	PRUNUS SALICINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4149	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%.
4150	PRUNUS SPINOSA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa. The concentration of Amygdalin in

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			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%.
4151	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4152	PSEUDOCYDONIA SINENSIS	A, H	
4153	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4154	PSEUDOTSUGA MENZIESII	A, H	
4155	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4156	PSIDIUM GUAJAVA	A, E, H	
4157	PSORALEN (OF CULLEN CORYLIFOLIUM)	E	
4158	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4159	PSYLLIUM HUSK DRY	A, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			label: - (PSYLL) 'On medical advice' (or words to that effect).
4160	PSYLLIUM HUSK POWDER	A, E, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4161	PSYLLIUM SEED DRY	A, E, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4162	PTELEA TRIFOLIATA	A, H	
4163	PTEROCARPUS MARSUPIUM	A, H	
4164	PTEROCARPUS SANTALINUS	A, E, H	
4165	PUERARIA LOBATA	A, E, H	
4166	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4167	PULLULAN	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4168	PUMICE	E	
4169	PUMPKIN	E	
4170	PUMPKIN SEED	E, H	
4171	PUMPKIN SEED OIL	E, H	
4172	PUNICA GRANATUM	A, E, H	
4173	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4174	PURIFIED HONEY	A, E	When the route of administration is oral, the medicine requires the following warning statement on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4175	PURIFIED SILICEOUS EARTH	E, H	
4176	PURIFIED TALC	E	
4177	PURIFIED WATER	E	
4178	PVM/MA COPOLYMER	E	
4179	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4180	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4181	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4182	PYRETHRINS	E	Only for use in topical medicines for dermal application. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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).
4183	PYRIDOXAL 5-PHOSPHATE	A, E	Pyridoxine is a mandatory component of Pyridoxal 5-phosphate. The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. 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].'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4184	PYRIDOXAL 5-PHOSPHATE MONOHYDRATE	A	Pyridoxine is a mandatory component of Pyridoxal 5-phosphate monohydrate. The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. 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].'
4185	PYRIDOXINE HYDROCHLORIDE	A, E, H	When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of Pyridoxine hydrochloride.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The percentage of pyridoxine from pyridoxine hydrochloride should be calculated based on the molecular weight of pyridoxine hydrochloride. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. 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].'
4186	PYROGLUTAMIC ACID	E	
4187	PYROLA DECORATA	A, H	
4188	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%.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
4189	PYRROSIA LINGUA	A, H	
4190	PYRROSIA PETIOLOSA	A, H	
4191	PYRROSIA SHEARERI	A, H	
4192	PYRUS COMMUNIS	A, E, H	Arbutin is a mandatory component of Pyrus communis. When for internal use, the concentration of arbutin in the medicine must not be more than 10 mg/Kg or 10 mg/L or 0.001%. When for topical use, the concentration of arbutin in the medicine must not be more than 10 mg/Kg or 10 mg/L or 0.001% unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must not be more than 0.3%.
4193	PYRUS PYRIFOLIA	A, H	Arbutin is a mandatory component of Pyrus pyrifolia. When for internal use, the concentration of arbutin in the medicine must not be more than 10 mg/Kg or 10 mg/L or 0.001%. When for topical use, the concentration of arbutin in the medicine must not be more than 10

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			mg/Kg or 10 mg/L or 0.001% unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must not be more than 0.3%.
4194	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%.
4195	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%.
4196	QUASSIA AMARA	A, E, H	
4197	QUASSIA WOOD JAMAICAN DRY	A, H	
4198	QUASSIA WOOD JAMAICAN	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	POWDER		
4199	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4200	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4201	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4202	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.
4203	QUATERNIUM-80	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4204	QUERCETIN	A	
4205	QUERCETIN DIHYDRATE	A	
4206	QUERCUS ACUTISSIMA	A, H	
4207	QUERCUS ALBA	A, E, H	
4208	QUERCUS PALUSTRIS	A, H	
4209	QUERCUS ROBUR	A, H	
4210	QUERCUS RUBRA	A, H	
4211	QUERCUS VIRGINIANA	A, H	
4212	QUILLAIA DRY	A, H	
4213	QUILLAIA POWDER	A, E, H	
4214	QUILLAJA SAPONARIA	A, H	
4215	QUINCE	E	
4216	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.
4217	QUININE SULFATE DIHYDRATE	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			Quinine is a mandatory component of quinine sulfate dihydrate. The maximum recommended daily dose must be no more than 50 mg of quinine.
4218	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4219	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4220	QUISQUALIS INDICA	A, H	
4221	R-ALPHA LIPOIC ACID	A	
4222	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%.
4223	RACEMIC CAMPHOR	E, H	Only for use as an active homoeopathic or excipient

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredient. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
4224	RADISH	E	
4225	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 5%.
4226	RANUNCULUS BULBOSUS	A, H	
4227	RANUNCULUS FICARIA	A, H	
4228	RANUNCULUS TERNATUS	A, H	
4229	RAPE OIL/TUNG OIL COPOLYMER	E	Only for use in topical medicines for dermal application and not for use in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4230	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%.
4231	RAPHANUS SATIVUS	A, H	
4232	RASPBERRY	E	
4233	RASPBERRY BRANDY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
4234	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%.
4235	RASPBERRY ESSENCE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4236	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%.
4237	RAUWOLFIA SERPENTINA	A, H	The concentration of equivalent dry Rauwolfia serpentina in the medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			10mg/Kg or 10mg/L or 0.001%.
4238	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%.
4239	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%.
4240	RED 27	E	Permitted for use only as a colour for oral and topical use. The concentration in the medicine must be no more than 0.5%.
4241	RED 27 ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use. The concentration in the medicine must be no more than 0.5%.
4242	RED ANT	H	Only for use as an active homoeopathic ingredient.
4243	RED CLOVER FLOWER DRY	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4244	RED CLOVER FLOWER POWDER	A, H	
4245	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4246	RED DEER	A	
4247	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4248	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4249	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4250	REHMANNIA GLUTINOSA	A, E, H	
4251	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%.
4252	RESORCINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
4253	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%.
4254	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'
4255	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'
4256	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4257	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4258	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%.
4259	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			serious bowel problems'.
4260	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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'.
4261	RHATANY ROOT DRY	A, H	
4262	RHATANY ROOT POWDER	A, H	
4263	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (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'.
4264	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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’.
4265	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4266	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4267	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4268	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%.
4269	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%.
4270	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			more than 70% ethanol v/v.
4271	RHODODENDRON AUREUM	A, H	
4272	RHODODENDRON FERRUGINEUM	A, H	Arbutin is a mandatory component of Rhododendron ferrugineum. When for internal use, the concentration of arbutin in the medicine must not be more than 10 mg/Kg or 10 mg/L or 0.001%. When for topical use, the concentration of arbutin in the medicine must not be more than 10 mg/Kg or 10 mg/L or 0.001% unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must not be more than 0.3%.
4273	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4274	RHUBARB	E, H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			[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'.
4275	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:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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'.
4276	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (LAX2) 'Prolonged use may cause serious bowel problems'.
4277	RHUS AROMATICA	A, E, H	
4278	RHUS CHINENSIS	A, H	
4279	RHUS GLABRA	A, E, H	
4280	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4281	RIBES GROSSULARIA	A, E, H	
4282	RIBES NIGRUM	A, E, H	
4283	RIBOFLAVIN	A, E	
4284	RIBOFLAVIN SODIUM PHOSPHATE	A, E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’
4285	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
4286	RIBOFLAVINE	A, E	
4287	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4288	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4289	RIBOSE	A	Only for use in oral medicines. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4290	RICE	E	
4291	RICE BRAN	E	
4292	RICE BRAN OIL	E	
4293	RICE BRAN WAX	A, E, H	
4294	RICE STARCH	E	
4295	RICE VINEGAR	E	
4296	RICE WINE	E	Ethanol is a mandatory component of Rice wine. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
4297	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4298	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4299	ROBINIA PSEUDOACACIA	A, E, H	When the herbal substance is

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			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.
4300	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4301	ROSA ARVENSIS	A, E, H	
4302	ROSA CANINA	A, E, H	
4303	ROSA CYMOSA	A, E, H	
4304	ROSA EGLANTERIA	A, E, H	
4305	ROSA GALLICA	A, E, H	
4306	ROSA LAEVIGATA	A, E, H	
4307	ROSA MULTIFLORA	A, E, H	
4308	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4309	ROSA RUGOSA	A, E, H	
4310	ROSA VILLOSA	A, E, H	
4311	ROSA X CENTIFOLIA	A, E, H	
4312	ROSA X DAMASCENA	A, E, H	
4313	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%.
4314	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%.
4315	ROSE FRUIT FRESH	A, E, H	
4316	ROSE HIP	E	
4317	ROSE OIL	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4318	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%.
4319	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%.
4320	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
4321	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'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4322	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'.
4323	ROYAL JELLY LYOPHILISED	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly lyophilised. The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4324	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4325	RUBIA CORDIFOLIA	A, H	
4326	RUBIA TINCTORUM	A, H	
4327	RUBUS CHINGII	A, H	
4328	RUBUS CORCHORIFOLIUS	A, H	
4329	RUBUS COREANUS	A, E, H	
4330	RUBUS FRUTICOSUS	A, E, H	
4331	RUBUS IDAEUS	A, E, H	
4332	RUBUS OCCIDENTALIS	A, E, H	
4333	RUBUS PARVIFOLIUS	A, H	
4334	RUBUS ROSIFOLIUS	A, H	
4335	RUDBECKIA HIRTA	A, H	
4336	RUE OIL	A, H	
4337	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
4338	RUMEX ACETOSA	A, H	
4339	RUMEX ACETOSELLA	A, H	
4340	RUMEX CONGLOMERATUS	A, H	
4341	RUMEX CRISPUS	A, E, H	
4342	RUMEX PULCHER	A, H	
4343	RUMEX SCUTATUS	A, H	
4344	RUSCUS ACULEATUS	A, H	
4345	RUTA GRAVEOLENS	A, E, H	
4346	RUTOSIDE	A, E	
4347	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4348	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4349	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%.
4350	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%.
4351	SACCHARIDE ISOMERATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			eye or on damaged skin. The concentration in the medicine must be no more than 3.66%.
4352	SACCHARIN	E	The medicine requires the following warning statement on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect).
4353	SACCHARIN SODIUM	E	The medicine requires the following warning statement on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect). When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’
4354	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			be no more than 1%.
4355	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4356	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%.
4357	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4358	SACCHARUM OFFICINARUM	A, E, H	
4359	SAFFLOWER OIL	A, E, H	
4360	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4361	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4362	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%.
4363	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’
4364	SAGE OIL SPANISH	A, E, H	
4365	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 0.002%.
4366	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%.
4367	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4368	SALIX ALBA	A, E, H	
4369	SALIX DAPHNOIDES	A, H	
4370	SALIX DISCOLOR	A, H	
4371	SALIX FRAGILIS	A, H	
4372	SALIX NIGRA	A, H	
4373	SALIX PURPUREA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4374	SALSOLA KALI	A, H	
4375	SALVIA CHINENSIS	A, H	
4376	SALVIA FRUTICOSA	A, H	
4377	SALVIA HISPANICA	A, E, H	
4378	SALVIA LAVANDULAEFOLIA	A, H	
4379	SALVIA MILTIORRHIZA	A, H	
4380	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%.
4381	SALVIA SCLAREA	A, E, H	
4382	SAMBUCUS CANADENSIS	A, H	
4383	SAMBUCUS EBULUS	A, H	
4384	SAMBUCUS NIGRA	A, E, H	
4385	SANDALWOOD OIL EAST INDIAN	A, E, H	
4386	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4387	SANICULA EUROPAEA	A, H	
4388	SANTALUM ALBUM	A, E, H	
4389	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.
4390	SAPINDUS MUKOROSSI	A, H	
4391	SAPONARIA OFFICINALIS	A, H	
4392	SAPOSHNIKOVIA DIVARICATA	A, H	
4393	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%.
4394	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
4395	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.
4396	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%.
4397	SATUREIA HORTENSIS	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4398	SATUREIA MONTANA	A, H	
4399	SAUROPUS SPATULIFOLIUS	A, H	
4400	SAURURUS CHINENSIS	A, H	
4401	SAUSSUREA COSTUS	A, H	
4402	SAVORY OIL SUMMER	A, H	
4403	SAXIFRAGA GRANULATA	A, E, H	
4404	SCAPHIUM SCAPHIGERUM	A, H	
4405	SCHEFFLERA HEPTAPHYLLA	A, H	
4406	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4407	SCHINUS MOLLE	A, H	
4408	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%.
4409	SCHISANDRA CHINENSIS	A, E, H	
4410	SCHIZONEPETA TENUIFOLIA	A, E, H	
4411	SCHOENOCAULON OFFICINALE	A, H	The maximum recommended daily dose must contain no more than the equivalent of 1mg of the dry herbal material.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4412	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%.
4413	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%.
4414	SCLERANTHUS ANNUUS	A, H	
4415	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4416	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%.
4417	SCROPHULARIA NINGPOENSIS	A, H	
4418	SCROPHULARIA NODOSA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4419	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4420	SCUTELLARIA BAICALENSIS	A, E, H	
4421	SCUTELLARIA BARBATA	A, H	
4422	SCUTELLARIA LATERIFLORA	A, E, H	
4423	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%.
4424	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%.
4425	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4426	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. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4427	SEDUM ACRE	A, H	
4428	SELAGINELLA TAMARISCINA	A, H	
4429	SELENICEREUS GRANDIFLORUS	A, E, H	
4430	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4431	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.'
4432	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'
4433	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4434	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.
4435	SEMOLINA	E	
4436	SEMPERVIVUM TECTORUM	A, H	
4437	SENEGA ROOT DRY	A, H	
4438	SENEGA ROOT POWDER	A, H	
4439	SENNA ALEXANDRINA	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna alexandrina.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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'.
4440	SENNA FRUIT ALEXANDRIAN DRY	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			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'.
4441	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			serious bowel problems'.
4442	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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'.
4443	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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'.
4444	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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'.
4445	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			serious bowel problems'.
4446	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:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (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'.
4447	SENNA TORA	A, H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			[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'.
4448	SEPIA	H	Only for use as an active homoeopathic ingredient.
4449	SEQUOIA SEMPERVIRENS	A, H	
4450	SEQUOIADENDRON GIGANTEUM	A, H	
4451	SERENOA REPENS	A, H	
4452	SERINE	A, E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4453	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4454	SESAME OIL	A, E, H	
4455	SESAME SEED	E	
4456	SESAMUM INDICUM	A, E, H	
4457	SETARIA ITALICA	A, H	
4458	SHARK CALCIUM CHONDROITIN SULFATE	A	
4459	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)
4460	SHARK CHONDROITIN SULFATE	A	
4461	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4462	SHARK SODIUM CHONDROITIN SULFATE	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4463	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			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.'
4464	SHEA BUTTER	E	
4465	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4466	SHELLAC	E	
4467	SHEPHERD'S PURSE HERB DRY	A, H	
4468	SHEPHERD'S PURSE HERB POWDER	A, H	
4469	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4470	SIGESBECKIA ORIENTALIS	A, E, H	
4471	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%.
4472	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%.
4473	SILICA SILYLATE	E	Only for use in topical medicines for dermal application.
4474	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4475	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4476	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).
4477	SILVER	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 1%.
4478	SILVER BEET	E, H	
4479	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			medicine must be no more than 1%.
4480	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4481	SILYBUM MARIANUM	A, E, H	
4482	SIMABA CEDRON	A, H	
4483	SIMETHICONE	E	
4484	SIMMONDSIA CHINENSIS	A, E, H	
4485	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%.
4486	SINAPIS ARVENSIS	A, H	
4487	SINOMENIUM ACUTUM	A, H	
4488	SIPHONESTEGIA CHINENSIS	A, H	
4489	SIRAITIA GROSVENORII	A, E, H	
4490	SISYMBRIUM OFFICINALE	A, H	
4491	SKATOLE	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients 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%.
4492	SKIPJACK-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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'
4493	SLIPPERY ELM BARK DRY	A, H	
4494	SLIPPERY ELM BARK POWDER	A, E, H	
4495	SMILAX ARISTOLOCHIIFOLIA	A, H	
4496	SMILAX CHINA	A, H	
4497	SMILAX GLABRA	A, H	
4498	SMILAX OFFICINALIS	A, E, H	

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
4499	SMILAX ORNATA	A, E, H	
4500	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%.
4501	SODIUM ACETATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4502	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%.
4503	SODIUM ACID CITRATE	A, E, H	When used as an active ingredient, only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When used as an active, only for use in oral medicines. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4504	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%.
4505	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).
4506	SODIUM ACRYLOYDIMETHYLTAURATE/	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	VP CROSSPOLYMER		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).
4507	SODIUM ALGINATE	E	
4508	SODIUM ASCORBATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4509	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%.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
4510	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%.
4511	SODIUM BENZOATE	E	Medicines containing benzoates require the following warning statement on the medicine label: - (TBNZO8) ‘Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or ‘Contains [insert the approved name of benzoate used]’ (or words to this effect) if product contains one benzoate source. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4512	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4513	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4514	SODIUM BICARBONATE	A, E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms. Medicines for use as oral rehydration therapy are subject to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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 medicine requires the following warning statements 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).' - (DIAR3) 'If diarrhoea persists, seek medical advice.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4515	SODIUM BISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4516	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4517	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4518	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4519	SODIUM CARBONATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4520	SODIUM CARBONATE MONOHYDRATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4521	SODIUM CARBOXYMETHYL BETAGLUCAN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			use in the eye. The concentration in the medicine must be no more than 0.005%.
4522	SODIUM CARRAGEENAN	E	
4523	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%.
4524	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4525	SODIUM CHLORIDE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			(or words to that effect). 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.
4526	SODIUM CHONDROITIN SULFATE	E	Only for use in topical medicines for dermal 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%.
4527	SODIUM CITRATE	A, E	Only for oral use when used as an active ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4528	SODIUM CITRATE DIHYDRATE	A, E	Only for oral use when used as an active ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4529	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%.
4530	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4531	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4532	SODIUM CYCLAMATE	E	When for oral or sublingual use and the total amount of sodium from all

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4533	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4534	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%.
4535	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4536	SODIUM ERYTHORBATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4537	SODIUM ETHYL HYDROXYBENZOATE	E	
4538	SODIUM FLUORIDE	A, E, H	Fluoride is a mandatory component of Sodium fluoride. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When used as an active ingredient, it is subject to the following conditions: a) Only for use in combination with at least one other listable therapeutically active ingredient. b) The concentration of fluoride ion must be no more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label: - (DNTSW) 'Do not swallow.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.' When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4539	SODIUM FUMARATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4540	SODIUM GLYCEROPHOSPHATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4541	SODIUM HYALURONATE	E	Only for use in topical medicines for dermal application.
4542	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4543	SODIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4544	SODIUM HYDROXYCITRATE	A	
4545	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%.
4546	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4547	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of Sodium hypochlorite. The concentration of chlorine in the medicine must be no more than 4%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			sodium' (or words to that effect).
4548	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4549	SODIUM LACTATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4550	SODIUM LAURETH SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4551	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%.
4552	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%.
4553	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4554	SODIUM LAURYL PHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4555	SODIUM LAURYL SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4556	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4557	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4558	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%.
4559	SODIUM METABISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4560	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 be no more than 0.01%.
4561	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 2%.
4562	SODIUM METHYL HYDROXYBENZOATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4563	SODIUM MOLYBDATE DIHYDRATE	A	Only for use in oral medicines. Molybdenum is a mandatory component of Sodium molybdate dihydrate.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
4564	SODIUM MONOFLUOROPHOSPHATE	A	Fluoride is a mandatory component of sodium monofluorophosphate. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When used as an active ingredient, it is subject to the following conditions: a) Only for use in combination with at least one other listable therapeutically active ingredient. b) The concentration of fluoride ion must be no more than 1,500 mg/kg. When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label: - (DNTSW) 'Do not swallow.' - (CHILD4) 'Do not use [this

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			product/insert name of product] in children 6 years of age or less.' When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4565	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%.
4566	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4567	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4568	SODIUM PANTOTHENATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4569	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4570	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 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 for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4571	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.
4572	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4573	SODIUM POLYMETAPHOSPHATE	E	
4574	SODIUM PROPIONATE	E	Only for use in topical medicines for dermal application.
4575	SODIUM PROPYL HYDROXYBENZOATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			[state quantity and units] of sodium' (or words to that effect). Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4576	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%.
4577	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'
4578	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.'
4579	SODIUM SELENITE	A, H	Selenium is a mandatory component of Sodium selenite.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.'
4580	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.'

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
4581	SODIUM SILICATE	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. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4582	SODIUM STARCH GLYCOLLATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
4583	SODIUM STARCH GLYCOLLATE TYPE A	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4584	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4585	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%.
4586	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%.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
4587	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4588	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%.
4589	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4590	SODIUM SULFATE	A, E, H	When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label: - (LAX4) 'Substance may have a laxative effect'. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			[state quantity and units] of sodium' (or words to that effect).
4591	SODIUM SULFATE DECAHYDRATE	A, E, H	When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label: - (LAX4) 'Substance may have a laxative effect'. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4592	SODIUM SULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4593	SODIUM SULFITE HEPTAHYDRATE	E	Only for use in topical medicines for dermal application. Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4594	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			eye. The concentration in the medicine must be no more than 5%.
4595	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.
4596	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.
4597	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 0.02%.
4598	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.
4599	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.
4600	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			solanine.
4601	SOLIDAGO GIGANTEA	A, H	
4602	SOLIDAGO GIGANTEA MIS	A, E, H	
4603	SOLIDAGO VIRGAUREA	A, E, H	
4604	SOLUBLE MAIZE STARCH	E	
4605	SOLUBLE POTATO STARCH	E	
4606	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4607	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4608	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4609	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%.
4610	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4611	SOPHORA FLAVESCENS	A, E, H	
4612	SOPHORA TONKINENSIS	A, H	
4613	SORBIC ACID	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4614	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4615	SORBITAN MONO-OLEATE	E	
4616	SORBITAN MONOLAURATE	E	
4617	SORBITAN MONOSTEARATE	E	
4618	SORBITAN OLEATE	E	
4619	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 10%.
4620	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%.
4621	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4622	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4623	SORBITAN STEARATE	E	
4624	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.
4625	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea' (or words to that effect).
4626	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. When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			[insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).'
4627	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. When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).'
4628	SORBUS AUCUPARIA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4629	SORBUS DOMESTICA	A, H	
4630	SORGHUM	E	
4631	SORGHUM VULGARE	A, H	
4632	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4633	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%.
4634	SOY POLYSACCHARIDE	E	
4635	SOY PROTEIN	E	
4636	SOY STEROL	E	
4637	SOYA BEAN	E	
4638	SOYA BRAN	E	
4639	SOYA OIL	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4640	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%.
4641	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%.
4642	SPARGANIUM STOLONIFERUM	A, H	
4643	SPARTIUM JUNCEUM	A, H	
4644	SPATHOLOBUS SUBERECTUS	A, H	
4645	SPEARMINT OIL	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of spearmint oil. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) 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; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4646	SPEARMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. Menthol is a mandatory component of spearmint oil terpeneless. When the medicine is for topical use: a) the medicine must not be intended for use in the eye or on damaged skin; b) the maximum concentration of menthol must not exceed 5%; and c) the medicine requires the following warning statements 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; and - (EYE) Avoid contact with eyes

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			(or words to that effect). When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4647	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%.
4648	SPIGELIA ANTHELMIA	A, H	
4649	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4650	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
4651	SPINACH	E	
4652	SPINACIA OLERACEA	A, E, H	
4653	SPIRODELA POLYRRHIZA	A, H	
4654	SPIRULINA	E	
4655	SPRAY-DRIED GLUCOSE SYRUP	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%.
4656	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4657	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%.
4658	SQUALANE	E	Only for use in topical medicines for dermal application.
4659	SQUALENE	A, E	
4660	SQUID OIL	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'. Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in combination with other ingredients in the medicine and be presented in a therapeutic dosage form for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			therapeutic use.
4661	SQUILL DRY	A, H	
4662	SQUILL INDIAN DRY	A, H	
4663	SQUILL INDIAN POWDER	A, H	
4664	SQUILL POWDER	A, H	
4665	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.'
4666	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.'
4667	ST JOHN'S WORT HERB	A, H	When used for oral ingestion, the medicine requires the following

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	POWDER		warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4668	STACHYS OFFICINALIS	A, E, H	
4669	STACHYS PALUSTRIS	A, H	
4670	STACHYURUS HIMALAICUS	A, H	
4671	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%.
4672	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4673	STAR ANISE OIL	A, E	When the concentration in the medicine is more than 50% and the nominal capacity of the container is equal to or less than 50mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4674	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%.
4675	STARCH SODIUM OCTENYL SUCCINATE	E	
4676	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4677	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4678	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4679	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4680	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4681	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).
4682	STEARETH-10	E	Only for use in topical medicines for dermal application.
4683	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%.
4684	STEARETH-2	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4685	STEARETH-20	E	Only for use in topical medicines for dermal application.
4686	STEARETH-21	E	Only for use in topical medicines for dermal application.
4687	STEARETH-5	E	Only for use in topical medicines for dermal application.
4688	STEARIC ACID	E	
4689	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%.
4690	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%.
4691	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
4692	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4693	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4694	STEARYL ALCOHOL	E	
4695	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).
4696	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4697	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4698	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%.
4699	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4700	STELLARIA CHAMAEJASME	A, H	
4701	STELLARIA DICHOTOMA	A, H	
4702	STELLARIA MEDIA	A, E, H	
4703	STEMONA JAPONICA	A, H	
4704	STEMONA SESSILIFOLIA	A, H	
4705	STENOTAPHRUM SECUNDATUM	A, H	
4706	STEPHANIA TETRANDA	A, H	
4707	STERCULIA	A, H	
4708	STERCULIA TRAGACANTHA	A, H	
4709	STERCULIA URENS	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4710	STEVIA REBAUDIANA	A, E, H	
4711	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4712	STILLINGIA SYLVATICA	A, H	
4713	STORAX PREPARED	A, E, H	
4714	STRAWBERRY	E	
4715	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%.
4716	STREPTOCOCCUS SALIVARIUS	A	Permitted for use in only oral medicines and only when the strain of Streptococcus salivarius is confirmed to be K12. The name of 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'.
4717	STREPTOCOCCUS	A	

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
	THERMOPHILUS		
4718	STROBILANTHES CUSIA	A, H	
4719	STRONG AMMONIA SOLUTION	E	Ammonia is a mandatory component of dilute ammonia solution. The concentration of ammonia in the medicine must be no more than 0.5%. When for internal use, the concentration in the medicine must be no more than 0.25%.
4720	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4721	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4722	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4723	STRYCHNOS IGNATII	H	Only for use as an active homoeopathic ingredient. Strychnine (of Strychnos spp.) is a mandatory component of Strychnos ignatii.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4724	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%.
4725	STYPHNOLOBIUM JAPONICUM	A, E, H	
4726	STYRAX BENZOIN	A, E, H	
4727	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%.
4728	STYRAX PARALLELONEURUM	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4729	STYRAX TONKINENSIS	A, H	
4730	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%.
4731	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4732	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%.
4733	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4734	SUCCINIC ACID	E	
4735	SUCRALOSE	E	
4736	SUCROSE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose,

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
4737	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%.
4738	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 0.3%.
4739	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%.
4740	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4741	SUCROSE LAURATE	E	When for oral or sublingual use, Sucrose is a mandatory component of Sucrose laurate. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4742	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4743	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4744	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).
4745	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
4746	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%.
4747	SUDAN III	E	Permitted for use only as a colour for topical use.
4748	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			women' (or words to that effect).
4749	SUGARCANE	E, H	When for oral or sublingual use, sucrose is a mandatory component of Sugarcane. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4750	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
4751	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%.
4752	SULFUR DIOXIDE	E	Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4753	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4754	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4755	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%.
4756	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 be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (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).
4757	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 be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			supplied after 1 July 2019: - (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).
4758	SUNFLOWER OIL	A, E, H	
4759	SUNFLOWER SEED	E, H	
4760	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4761	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4762	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4763	SWEDE	E	
4764	SWEET ORANGE OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
4765	SWEET POTATO	E	
4766	SWERTIA CHIRATA	A, H	
4767	SWIETENIA MAHOGANI	A, H	
4768	SYAGRUS ROMANZOFFIANA	A, E, H	
4769	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%.
4770	SYMPLOCARPUS FOETIDUS	A, H	
4771	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4772	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.
4773	SYNTHETIC WAX	E	
4774	SYRINGA RETICULATA	A, H	
4775	SYRINGA VULGARIS	A, H	
4776	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When the plant preparation is oil or distillate, the concentration of oil or distillate in the product is greater than 25% and the nominal capacity of the container is less than 15 millilitres, a restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate and the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of the oil or distillate and the concentration of oil or distillate in the product must not be greater than 25%.
4777	SYZYGIUM CUMINI	A, H	
4778	TABEBUIA SERRATIFOLIA	A, E, H	
4779	TAGETES ERECTA	A, H	
4780	TAGETES MINUTA	A, E, H	
4781	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%.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
4782	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4783	TALLOW	E	Only for use in topical medicines for dermal application.
4784	TALLOW GLYCERIDES	E	
4785	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%.
4786	TAMARIX APHYLLA	A, H	
4787	TAMARIX CHINENSIS	A, H	
4788	TAMARIX GALLICA	A, H	
4789	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			Tamus communis.
4790	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4791	TANACETUM PARTHENIUM	A, E, H	
4792	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%.
4793	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%.
4794	TANGERINE OIL COLDPRESSED	A, E, H	When used internally, oxedrine is a mandatory component of tangerine oil coldpressed.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
4795	TANNIC ACID	E	
4796	TAPIOCA STARCH	E	
4797	TARAXACUM MONGOLICUM	A, E, H	
4798	TARAXACUM OFFICINALE	A, E, H	
4799	TARO	E	
4800	TARRAGON OIL	A, E, H	
4801	TARTARIC ACID	E	
4802	TARTRAZINE	E	Permitted for use only as a colour for oral and topical use. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4803	TARTRAZINE ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use. The medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (TART) 'Contains tartrazine' (or words to that effect).
4804	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%.
4805	TAURINE	A, E	
4806	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4807	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)

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (CHILD2) 'Not suitable for children'.
4808	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4809	TERMINALIA CATAPPA	A, H	
4810	TERMINALIA CHEBULA	A, H	
4811	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%.
4812	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
4813	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%.
4814	TERPINEOL	E	
4815	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
4816	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%.
4817	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%.
4818	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 5%.
4819	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%.
4820	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4821	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%.
4822	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4823	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%.
4824	TETRACLINIS ARTICULATA	A, E, H	
4825	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%.
4826	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.
4827	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%.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
4828	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%.
4829	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%.
4830	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%.
4831	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4832	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%.
4833	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%.
4834	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%.
4835	TETRAHYDROMUGUOL	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4836	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%.
4837	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4838	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%.
4839	TETRAPANAX PAPYRIFER	A, H	

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
4840	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4841	TETRASODIUM PYROPHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4842	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4843	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4844	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4845	THAPSIA GARGANICA	A, H	
4846	THAUMATIN	E	
4847	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%.
4848	THEMEDA TRIANDRA	A, H	
4849	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma cacao. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
4850	THEOBROMA OIL	A, E, H	
4851	THIAMINE	A, E	
4852	THIAMINE HYDROCHLORIDE	A, E	
4853	THIAMINE NITRATE	A, E	
4854	THIOCINEOLE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4855	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%.
4856	THLASPI ARVENSE	A, E, H	
4857	THREONINE	A, E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4858	THUJA OCCIDENTALIS	A, H	
4859	THUJA PLICATA	A, E, H	
4860	THYME HERB DRY	A, E, H	
4861	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).
4862	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 topical medicines for dermal applications.
4863	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4864	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4865	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).
4866	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).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4867	THYMUS VULGARIS	A, E, H	When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4868	THYMUS VULGARIS MIS	A, E, H	When the plant preparation is an oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus vulgaris mis oil or distillate in the preparation is greated than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4869	THYMUS ZYGIS	A, H	When the plant preparation is an oil

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			or a distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus zygis oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4870	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4871	TILACTASE	A	Must be derived from Aspergillus oryzae and comply with the relevant USP monograph. When the dosage form is undivided, the units 'acid lactase units per gram' and 'Thousand acid lactase units per gram' are permitted. When the dosage form is divided, the units 'acid lactase units' and 'thousand acid lactase units' are permitted.
4872	TILIA CORDATA	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4873	TILIA PLATYPHYLLOS	A, E, H	
4874	TILIA TOMENTOSA	A, H	
4875	TILIA X VULGARIS	A, E, H	
4876	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%.
4877	TIN	H	Only for use as an active homoeopathic ingredient.
4878	TINOSPORA CORDIFOLIA	A, H	
4879	TINOSPORA SINENSIS	A, H	
4880	TITANIUM DIOXIDE	A, E	For use as an active ingredient only in sunscreens for dermal application. The concentration in sunscreens must be no more than 25%. For use as an excipient only as a colour in oral medicines and as a colour in topical medicines for dermal application. Not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (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).
4881	TOCOCYSTEAMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 0.01%.
4882	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%
4883	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%.
4884	TOCOPHERYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			use on damaged skin or in the eye. The concentration in the medicine must be no more than 0.05%
4885	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4886	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%.
4887	TOLU BALSAM	A, E, H	
4888	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%.
4889	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
4890	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%.
4891	TOMATO	E	
4892	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%.
4893	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4894	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%.
4895	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4896	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.
4897	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4898	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4899	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4900	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%.
4901	TRAGACANTH	A, E	
4902	TRAMETES VERSICOLOR	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4903	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4904	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%.
4905	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.
4906	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			medicine must be no more than 1%.
4907	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%.
4908	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%.
4909	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4910	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%.
4911	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%.
4912	TRANS-2-HEXENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4913	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%.
4914	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%.
4915	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%.
4916	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 5%.
4917	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%.
4918	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%.
4919	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%.
4920	TRANS-ETHYL 2-OCTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4921	TRANS-METHYL-2-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4922	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of Treacle. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4923	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%.
4924	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
4925	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.
4926	TREMELLA FUCIFORMIS	A, H	
4927	TRIACETIN	E	
4928	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4929	TRIADICA SEBIFERA	A, H	
4930	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
4931	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. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4932	TRIBEHENIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			must be no more than 6%.
4933	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%.
4934	TRIBULUS TERRESTRIS	A, E, H	
4935	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%.
4936	TRICALCIUM PHOSPHATE	E	
4937	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%.
4938	TRICAPRYLYL CITRATE	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
4939	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4940	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%.
4941	TRICHODERMA VIRIDE	A, E, H	
4942	TRICHOSANTHES KIRILOWII	A, E, H	
4943	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
4944	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

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			medicine must be no more than 1%.
4945	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%.
4946	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4947	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%.
4948	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%.
4949	TRIDECYL BEHENATE	E	Behenic acid is a mandatory

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			component of Tridecyl behenate. Only for use in topical medicines for dermal application.
4950	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%.
4951	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%.
4952	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
4953	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
4954	TRIETHOXYCAPRYLYLSILANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			use in the eye or on damaged skin. The concentration in the medicine must be no more than 1%.
4955	TRIETHYL CITRATE	E	
4956	TRIETHYLENE GLYCOL	E	
4957	TRIFOLIUM PRATENSE	A, E, H	
4958	TRIFOLIUM REPENS	A, H	
4959	TRIGONELLA FOENUM-GRAECUM	A, E, H	
4960	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%.
4961	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
4962	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
4963	TRIISODECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4964	TRIISONONANOIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4965	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
4966	TRILAURIN	E	Only for use in topical medicines for dermal application.
4967	TRILISA ODORATISSIMA	A, H	
4968	TRILLIUM ERECTUM	A, H	
4969	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4970	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%.
4971	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%.
4972	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%.
4973	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4974	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%.
4975	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
4976	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%.
4977	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
4978	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient.
4979	TRIOCTANOIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			use in the eye. The concentration in the medicine must be no more than 5%.
4980	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%.
4981	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%.
4982	TRIOSTEUM PERFOLIATUM	A, H	
4983	TRIOXAUNDECANEDIOIC ACID	E	
4984	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4985	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%.
4986	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 be no more than 10%. When used topically, the dosage form must not be spray. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			statements on the medicine label if supplied after 1 July 2019: - (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).
4987	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%.
4988	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
4989	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4990	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%.
4991	TRISTEARIN	E	
4992	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. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4993	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. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			- (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4994	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%.
4995	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
4996	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
4997	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 be no more than 12%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (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).
4998	TROLLIUS CHINENSIS	A, H	
4999	TROMETAMOL	E	
5000	TROMETAMOL HYDROCHLORIDE	E	
5001	TROPAEOLUM MAJUS	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5002	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5003	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%.
5004	TSUGA CANADENSIS	A, H	
5005	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%.
5006	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5007	TURNERA DIFFUSA	A, E, H	Arbutin is a mandatory component of Turnera diffusa. When for internal use, the concentration of arbutin in the medicine must not be more than 10 mg/Kg or 10 mg/L or 0.001%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When for topical use, the concentration of arbutin in the medicine must not be more than 10 mg/Kg or 10 mg/L or 0.001% unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must not be more than 0.3%.
5008	TURNIP	E	
5009	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than 25%.
5010	TYPHA ANGUSTIFOLIA	A, H	
5011	TYPHA LATIFOLIA	A, H	
5012	TYPHONIUM GIGANTEUM	A, H	
5013	TYROSINE	A, E	