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

Note: See sections 5 and 6.

**Permissible ingredients and requirements**

| Column 1 | Column 2 | Column 3 | Column 4 |
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| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| 3643 | P-ALPHA-DIMETHYL STYRENE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3644 | 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.<br>The concentration in the medicine must be no more than 0.3%. |
| 3645 | PADIMATE O | A | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 8%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective |

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| | | | clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 3646 | PADINA PAVONICA THALLUS PHYTOSTEROLS | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.01%. |
| 3647 | PAEONIA LACTIFLORA | A, E, H | |
| 3648 | PAEONIA OBOVATA | A, H | |
| 3649 | PAEONIA SUFFRUTICOSA | A, E, H | |
| 3650 | PAEONIA VEITCHII | A, H | |
| 3651 | PALIURUS SPINA-CHRISTI | A, H | |
| 3652 | PALLADIUM | H | Only for use as an active homoeopathic ingredient. |
| 3653 | PALM FRUIT OIL | A, E, H | |
| 3654 | PALM GLYCERIDES | E | |
| 3655 | PALM KERNEL OIL | A, E, H | |
| 3656 | PALM TOCOTRIENOLS COMPLEX | A, H | |
| 3657 | PALMARIA PALMATA | A, H | |
| 3658 | PALMAROSA OIL | A, E, H | |
| 3659 | PALMIDROL | A | Only permitted for use in medicines limited to oral routes of administration.<br>The maximum recommended daily dose of the medicine must not provide more than 600 mg of palmidrol.<br>The following warning statements (or words to the same effect) are required on the medicine label:<br>- (ANALG) 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use.'<br>- (ADULT) ‘Adults only.’ |

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| | | | - (21DAYS) 'Not to be used for more than 21 consecutive days.' |
| 3660 | PALMITIC ACID | E | |
| 3661 | PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS | A | |
| 3662 | 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.<br>The concentration in the medicine must be no more than 0.002%. |
| 3663 | 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.<br>The concentration in the medicine must be no more than 0.01% |
| 3664 | PALMITOYL OLIGOPEPTIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.002%. |
| 3665 | PALMITOYL PENTAPEPTIDE-3 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.0005%. |
| 3666 | PALMITOYL TETRAPEPTIDE-3 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended |

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| | | | for use in the eye.<br>The concentration in the medicine must be no more than 0.001%. |
| 3667 | PANAX GINSENG | A, E, H | |
| 3668 | PANAX JAPONICUS | A, H | |
| 3669 | PANAX NOTOGINSENG | A, H | |
| 3670 | PANAX PSEUDOGINSENG | A, H | |
| 3671 | PANAX QUINQUEFOLIUS | A, H | |
| 3672 | PANICUM MILIACEUM | A, H | |
| 3673 | PANTETHINE | E | Only for use in topical medicines for dermal application. |
| 3674 | PANTHENOL | A, E | |
| 3675 | PANTHENYL ETHYL ETHER | E | Only for use in topical medicines for dermal application. |
| 3676 | PANTOLACTONE | E | |
| 3677 | PANTOTHENIC ACID | A, E | When used topically, the concentration in the medicine must be no more than 0.1%. |
| 3678 | PANTOTHENIC ACID POLYPEPTIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%. |
| 3679 | PAPAIN | A, E | |
| 3680 | PAPER | E | Only for use in topical medicines for dermal application. |
| 3681 | PAPRIKA OLEORESIN | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total |

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| | | | flavour concentration in a medicine must be no more than 5%. |
| 3682 | PARA-CRESOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3683 | PARA-CRESYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3684 | PARA-CRESYL ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3685 | PARA-CRESYL PHENYLACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3686 | PARA-CYMENE | E | Permitted for use only in |

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| | | | combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3687 | PARA-ETHOXYBENZALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3688 | PARA-ETHYL CRESOXYACETATE | E | Para-ethyl cresoxyacetate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.<br>The total concentration of the fragrance proprietary excipient formulation containing para-ethyl cresoxyacetate must not be more than 1% of the total medicine. |
| 3689 | PARA-ETHYLPHENOL | E | Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.<br>The maximum recommended daily dose must contain no more than 0.12 mg of para-ethylphenol.<br>The total flavour proprietary excipient formulation in a medicine must be no more than 5%. |
| 3690 | PARA-HYDROXY | E | Permitted for use only in |

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| | BENZALACETONE | | combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3691 | PARA-HYDROXYBENZOIC ACID | E | |
| 3692 | PARA-MENTHA-8-THIOL-3-ONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3693 | PARA-METHYL ACETOPHENONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3694 | PARA-METHYL ANISOLE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3695 | PARA-METHYL DIMETHYLBENZYL CARBINOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total |

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| | | | flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3696 | PARA-PROPYL ANISOLE | E | Para-propyl anisole must only be included in medicines when in combination with other permitted ingredients as a fragrance and/or flavour proprietary excipient formulation.<br>The total concentration of fragrance proprietary excipient formulations containing para-propyl anisole must not be more than 1% of the total medicine.<br>The total concentration of flavour proprietary excipient formulations containing para-propyl anisole must not be more than 5% of the total medicine. |
| 3697 | PARA-TERT-BUTYLCYCLOHEXYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3698 | PARA-TERT-BUTYLPHENYL-ALPHA-METHYLHYDROCINNAMIC ALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3699 | PARA-TOLUALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a |

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| | | | flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3700 | PARA-TOLYL ACETALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3701 | PARAMERIA LAEVIGATA | A, H | |
| 3702 | PARIETARIA JUDAICA | A, H | |
| 3703 | PARIS POLYPHYLLA | A, H | |
| 3704 | PARIS QUADRIFOLIA | A, H | |
| 3705 | PARSLEY | E, H | |
| 3706 | PARSLEY HERB DRY | A, E, H | |
| 3707 | PARSLEY HERB OIL | A, E, H | |
| 3708 | PARSLEY HERB POWDER | A, E, H | |
| 3709 | PARSLEY SEED OIL | A, E, H | |
| 3710 | PARTHENOCISSUS TRICUSPIDATA | A, H | |
| 3711 | PARTIALLY DEHYDRATED LIQUID SORBITOL | E | Sorbitol is a mandatory component of partially dehydrated liquid sorbitol.<br>Permitted for use only as part of the capsule in medicines where the dosage form is a soft capsule. |
| 3712 | PARTIALLY HYDROGENATED SOYA OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total |

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| | | | flavour concentration in the medicine must be no more than 5%. |
| 3713 | PARTIALLY REFINED PORPHYRA YEZOENSIS CYTOPLASM EXTRACT | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.00002%. |
| 3714 | PASPALUM NOTATUM | A, H | |
| 3715 | PASSIFLORA CAERULEA | A, H | |
| 3716 | PASSIFLORA EDULIS | E | |
| 3717 | PASSIFLORA HERB DRY | A, H | |
| 3718 | PASSIFLORA INCARNATA | A, E, H | |
| 3719 | PATCHOULI OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3720 | PATENT BLUE V | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 3721 | PATENT BLUE V ALUMINIUM LAKE | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 3722 | PATRINIA SCABIOSIFOLIA | A, H | |
| 3723 | PATRINIA VILLOSA | A, H | |
| 3724 | PAULLINIA CUPANA | A, E, H | Caffeine is a mandatory component of Paullinia cupana.<br>When the medicine is |

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

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| | | | medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:<br>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'<br>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect). |
| 3725 | PAULLINIA PINNATA | A, H | |
| 3726 | PAWPAW | E | |
| 3727 | PEA | E | |
| 3728 | PEA STARCH | E | |
| 3729 | PEACH | E | |
| 3730 | PEANUT | E | |
| 3731 | PEAR | E | |
| 3732 | PECAN | E | |
| 3733 | PECTIN | A, E | |
| 3734 | PEG-10 DIMETICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin.<br>The concentration in the medicine must be no more than 4.0%. |
| 3735 | PEG-10 SOYA STEROL | E | Only for use in topical medicines for dermal application. |
| 3736 | PEG-100 STEARATE | E | Only for use in topical medicines for dermal application. |
| 3737 | PEG-12 DILAURATE | E | |

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| 3738 | PEG-12 DIMETICONE/PPG-20 CROSSPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 2%. |
| 3739 | PEG-120 METHYL GLUCOSE DIOLEATE | E | Only for use in topical medicines for dermal application. |
| 3740 | PEG-120 STEARATE | E | Only for use in topical medicines for dermal application. |
| 3741 | PEG-15 COCAMINE | E | Only for use in topical medicines for dermal application. |
| 3742 | PEG-150 DISTEARATE | E | Only for use in topical medicines for dermal application. |
| 3743 | PEG-20 ALMOND GLYCERIDES | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.5%. |
| 3744 | PEG-20 METHYL GLUCOSE DISTEARATE | E | Only for use in topical medicines for dermal application. |
| 3745 | PEG-20 METHYL GLUCOSE SESQUISTEARATE | E | Only for use in topical medicines for dermal application. |
| 3746 | PEG-20 SORBITAN ISOSTEARATE | E | Only for use in topical medicines for dermal application. |

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| 3747 | PEG-20 STEARATE | E | Only for use in topical medicines for dermal application. |
| 3748 | PEG-25 PABA | A | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 10%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 3749 | PEG-30 DIPOLYHYDROXYSTEARATE | E | Only for use in topical medicines for dermal application. |
| 3750 | PEG-30 STEARATE | E | Only for use in topical medicines for dermal application. |
| 3751 | PEG-35 CASTOR OIL | E | |
| 3752 | PEG-4 DILAURATE | E | Only for use in topical medicines for dermal application. |
| 3753 | PEG-4 LAURATE | E | Only for use in topical medicines for dermal application.<br>Dioxane and Ethylene oxide are mandatory components of PEG-4 laurate.<br>The concentration of Dioxane in the medicine must be no |

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| | | | more than 10 mg/kg or 10 mg/L or 0.001%.<br>The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%. |
| 3754 | PEG-4 STEARATE | E | Only for use in topical medicines for dermal application. |
| 3755 | PEG-40 CASTOR OIL | E | |
| 3756 | PEG-40 HYDROGENATED CASTOR OIL | E | |
| 3757 | PEG-40 SORBITAN DIISOSTEARATE | E | Only for use in topical medicines for dermal application.<br>Dioxane and Ethylene oxide are mandatory components of PEG-40 sorbitan diisostearate.<br>The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.<br>The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%. |
| 3758 | PEG-40 STEARATE | E | Only for use in topical medicines for dermal application. |
| 3759 | PEG-45/DODECYL GLYCOL COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 3760 | PEG-5 GLYCERYL STEARATE | E | Only for use in topical medicines for dermal application. |
| 3761 | PEG-50 STEARATE | E | Only for use in topical medicines for dermal application. |
| 3762 | PEG-55 PROPYLENE GLYCOL | E | Only for use in topical |

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| | OLEATE | | medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.6%. |
| 3763 | PEG-6 LAURAMIDE | E | Only for use in topical medicines for dermal application. |
| 3764 | PEG-60 ALMOND GLYCERIDES | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration when used in medicines applied directly to the skin must be no more than 10%.<br>The concentration when used in bath oil medicines must be no more than 30%. |
| 3765 | PEG-60 GLYCERYL ISOSTEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 2%. |
| 3766 | PEG-60 HYDROGENATED CASTOR OIL | E | Only for use in topical medicines for dermal application. |
| 3767 | PEG-7 COCAMIDE | E | Only for use in topical medicines for dermal application. |
| 3768 | PEG-7 GLYCERYL COCOATE | E | Only for use in topical medicines for dermal application. |
| 3769 | PEG-7 HYDROGENATED | E | Only for use in topical |

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| | CASTOR OIL | | medicines for dermal application. |
| 3770 | PEG-75 LANOLIN | E | Only for use in topical medicines for dermal application. |
| 3771 | PEG-75 STEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 1.5%. |
| 3772 | PEG-8 CETYL DIMETHICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.0005%. |
| 3773 | PEG-8 DILAURATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 4%. |
| 3774 | PEG-8 DISTEARATE | E | Only for use in topical medicines for dermal application. |
| 3775 | PEG-8 LAURATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 4%.<br>The levels of possible |

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| | | | impurities such as ethylene oxide (and related material) must be kept below the level of detection. |
| 3776 | PEG-8 PROPYLENE GLYCOL COCOATE | E | |
| 3777 | PEG-8 STEARATE | E | Only for use in topical medicines for dermal application. |
| 3778 | PEG-9 POLYDIMETHYLSILOXYETHYL DIMETICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 3.5%. |
| 3779 | PEG/PPG-14/7 DIMETHYL ETHER | E | Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 7%. |
| 3780 | PEG/PPG-18/18 DIMETHICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 3781 | PELARGONIUM GRAVEOLENS | A, E, H | |
| 3782 | PELLITORINE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

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| 3783 | PELTIGERA CANINA | A, H | |
| 3784 | PENICILLIUM EXPANSUM | A, H | |
| 3785 | PENNYROYAL OIL | E | D-Pulegone/Pulegone is a mandatory component of Pennyroyal Oil.<br>The concentration of D Pulegone/ Pulegone in the medicine must be no more than 4%.<br>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in the medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.<br>When the medicine is for a use other than topical, the maximum recommended daily dose must be no more than 50 mg of Pennyroyal Oil. |
| 3786 | PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.018% |
| 3787 | PENTAERYTHRITYL TETRAISOSTEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 61%. |
| 3788 | PENTAERYTHRITYL | E | Only for use in topical |

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| | TETRALAURATE | | medicines for dermal application.<br>The concentration in the medicine must be no more than 80%. |
| 3789 | PENTAMETHYLHEPTENONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3790 | PENTANE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3791 | 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.<br>The concentration in the medicine must be no more than 0.1%. |
| 3792 | PENTYLENE GLYCOL | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 3793 | PEPPER BLACK | E, H | |
| 3794 | PEPPER OIL TERPENELESS | E | Permitted for use only in |

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| | | | combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3795 | PEPPER WHITE | E, H | |
| 3796 | PEPPERMINT AMERICAN EXT. | E | Menthol is a mandatory component of peppermint american ext.<br>When the medicine is for topical use for dermal application:<br>a) the medicine must not be intended for use in the eye or on damaged skin;<br>b) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>c) the following warning statement is required on the medicine label:<br>- (EYE) Avoid contact with eyes (or words to that effect).<br>d) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:<br>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;<br>- (IRRIT) If irritation develops, discontinue use.<br>e) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:<br>– (MENTH) Contains a high |

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| | | | concentration of menthol, which can cause severe skin irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol. |
| 3797 | PEPPERMINT LEAF DRY | A, E, H | Menthol is a mandatory component of peppermint leaf dry.<br>When the medicine is for topical use for dermal application:<br>(i) the medicine must not be intended for use in the eye or on damaged skin;<br>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>(iii) the following warning statement is required on the medicine label:<br>- (EYE) Avoid contact with eyes (or words to that effect).<br>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:<br>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;<br>- (IRRIT) If irritation develops, discontinue use.<br>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:<br>– (MENTH) Contains a high |

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| | | | concentration of menthol, which can cause severe skin irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol. |
| 3798 | PEPPERMINT LEAF POWDER | A, E, H | Menthol is a mandatory component of peppermint leaf powder.<br>When the medicine is for topical use for dermal application:<br>(i) the medicine must not be intended for use in the eye or on damaged skin;<br>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>(iii) the following warning statement is required on the medicine label:<br>- (EYE) Avoid contact with eyes (or words to that effect).<br>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:<br>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;<br>- (IRRIT) If irritation develops, discontinue use.<br>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:<br>– (MENTH) Contains a high |

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| | | | concentration of menthol, which can cause severe skin irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol. |
| 3799 | PEPPERMINT OIL | A, E, H | Menthol is a mandatory component of peppermint oil.<br>When the medicine is for topical use for dermal application:<br>(i) the medicine must not be intended for use in the eye or on damaged skin;<br>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>(iii) the following warning statement is required on the medicine label:<br>- (EYE) Avoid contact with eyes (or words to that effect).<br>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:<br>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;<br>- (IRRIT) If irritation develops, discontinue use.<br>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:<br>– (MENTH) Contains a high concentration of menthol, |

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| | | | which can cause severe skin irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol. |
| 3800 | PEPPERMINT OIL TERPENELESS | E | Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation.<br>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.<br>The total fragrance proprietary excipient formulation in a medicine must be no more 1%.<br>Menthol is a mandatory component of peppermint oil terpeneless.<br>When the medicine is for topical use for dermal application:<br>i) the medicine must not be intended for use in the eye or on damaged skin;<br>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>iii) the following warning statement is required on the medicine label:<br>- (EYE) Avoid contact with eyes (or words to that effect).<br>iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: |

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| | | | - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;<br>- (IRRIT) If irritation develops, discontinue use.<br>v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:<br>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol. |
| 3801 | PEPPERMINT OIL TERPENES AND TERPENOIDS | E | Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation.<br>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.<br>Menthol is a mandatory component of peppermint oil terpenes and terpenoids.<br>When the medicine is for topical use for dermal application:<br>i) the medicine must not be intended for use in the eye or on damaged skin;<br>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>iii) the following warning statement is required on the medicine label: |

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| | | | - (EYE) Avoid contact with eyes (or words to that effect).<br>iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:<br>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;<br>- (IRRIT) If irritation develops, discontinue use.<br>v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:<br>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol. |
| 3802 | PERFLUOROPOLYMETHYLISOPROPYL ETHER | E | Only for use in topical medicines for dermal application. |
| 3803 | 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.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3804 | PERILLA FRUTESCENS | A, E, H | |

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| 3805 | PERILLALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3806 | PERLITE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 2%. |
| 3807 | PERMETHRIN | E | The total concentration of permethrin in the medicine must not be more than 2%. |
| 3808 | PERSEA AMERICANA | A, E, H | |
| 3809 | PERSIC OIL | A, E, H | Amygdalin and Hydrocyanic acid are mandatory components of Persic oil.<br>The concentration of amygdalin in the medicine must be no more than 0%.<br>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |
| 3810 | PERSICARIA CHINENSIS | A, H | |
| 3811 | PERSICARIA TINCTORIA | A, H | |
| 3812 | PERSIMMON | E | |
| 3813 | PERU BALSAM | A, E, H | |
| 3814 | PERU BALSAM OIL | A, E, H | |
| 3815 | PETITGRAIN MANDARIN OIL | E | Permitted for use only in combination with other permitted ingredients as a |

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| | | | flavour<br>The final concentration of the oil in the flavour does not exceed 30%<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5% |
| 3816 | PETITGRAIN OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3817 | PETITGRAIN OIL CITRONNIER | E | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.<br>When included in a medicine for use on the lips the concentration of petitgrain oil citronnier must be no more than 0.1%.<br>When included in dermal creams for infant use the concentration of petitgrain oil citronnier must be no more than 0.5%<br>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 3818 | PETITGRAIN OIL PARAGUAY | A, E, H | When used internally, oxedrine is a mandatory component of petitgrain oil paraguay.<br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. |

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| 3819 | PETITGRAIN OIL TERPENELESS | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3820 | PETROSELINUM CRISPUM | A, E, H | |
| 3821 | PEUCEDANUM PRAERUPTORUM | A, E, H | |
| 3822 | PEUMUS BOLDUS | A, H | Volatile oil components (of Peumus boldus) is a mandatory component.<br>The maximum recommended daily dose must be no more than 100 mg of volatile oil components (of Peumus boldus). |
| 3823 | PHALARIS ARUNDINACEA | A, H | |
| 3824 | PHALARIS CANARIENSIS | A, H | |
| 3825 | PHASEOLUS COCCINEUS | A, H | |
| 3826 | PHASEOLUS VULGARIS | A, H | |
| 3827 | PHELLINUS ROBINIAE | A, E, H | |
| 3828 | PHELLODENDRON AMURENSE | A, E, H | |
| 3829 | PHELLODENDRON CHINENSE | A, H | |
| 3830 | PHENACETIN | E | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 0.1%. |
| 3831 | PHENETHYL 2-METHYLBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total |

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| | | | flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3832 | PHENETHYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3833 | PHENETHYL ALCOHOL | E | Permitted for use only:<br>a) in topical medicines for dermal application; and<br>b) for internal use in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.<br>The total flavour proprietary excipient formulation concentration in a medicine must be no more than 5%. |
| 3834 | PHENETHYL BENZOATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 6%. |
| 3835 | PHENETHYL DIMETHICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the |

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| | | | medicine must be no more than 0.2% |
| 3836 | PHENETHYL ISOAMYL ETHER | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3837 | PHENETHYL ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3838 | PHENETHYL ISOVALERATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3839 | PHENETHYL PHENYLACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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| 3840 | PHENETHYL SALICYLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3841 | PHENOL | E | Only for use in topical medicines for dermal application.<br>The concentration of phenol in the medicine must be no more than 1%. |
| 3842 | PHENOXYACETALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3843 | PHENOXYETHANOL | E | Only for use in topical medicines for dermal application.<br>The concentration of phenoxyethanol in the preparation must not exceed 15%. |
| 3844 | PHENOXYETHYL ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a |

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| | | | medicine must be no more 1%. |
| 3845 | PHENOXYETHYLPARABEN | E | Only for use in topical medicines for dermal application. |
| 3846 | PHENYL DIMETHICONE | E | Only for use in topical medicines for dermal application. |
| 3847 | PHENYL TRIMETHICONE | E | Only for use in topical medicines for dermal application. |
| 3848 | PHENYLACETALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3849 | PHENYLACETALDEHYDE DIMETHYL ACETAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3850 | PHENYLACETALDEHYDE GLYCERYLACETAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 3851 | PHENYLACETIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3852 | PHENYLALANINE | A, E | When the maximum recommended daily dose of the medicine provides more than 500 mg phenylalanine, the following warning statement is required on the medicine label:<br>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant'. |
| 3853 | 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.<br>The concentration in the medicine must not be more than 4%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 3854 | PHENYLETHYL BUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a |

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| | | | medicine must be no more than 5%. |
| 3855 | PHENYLETHYL CAPROATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3856 | PHENYLETHYL CAPRYLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3857 | PHENYLETHYL CINNAMATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3858 | PHENYLETHYL FORMATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3859 | PHENYLETHYL METHYLETHYL CARBINOL | E | Permitted for use only in combination with other |

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| | | | permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3860 | PHENYLETHYL PROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3861 | PHENYLETHYL TIGLATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3862 | PHENYLISOPROPYL DIMETICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 3863 | PHENYLPROPANOL | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.16%. |

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| 3864 | PHLEUM PRATENSE | A, H | |
| 3865 | PHLOXINE B | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 3866 | PHLOXINE B ALUMINIUM LAKE | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 3867 | PHOENIX DACTYLIFERA | A, E, H | |
| 3868 | PHOSPHATIDYL CHOLINE | E | |
| 3869 | PHOSPHOLIPIDS | E | Only for use in topical medicines for dermal application and not intended for use in the eye.<br>The concentration in the medicine must be no more than 20%. |
| 3870 | PHOSPHORIC ACID | E, H | The concentration in liquid medicines must be no more than 15%. |
| 3871 | PHOSPHORUS | H | Only for use as an active homoeopathic ingredient. |
| 3872 | PHOTINIA SERRULATA | A, H | |
| 3873 | PHRAGMITES AUSTRALIS | A, H | |
| 3874 | PHYLLANTHUS AMARUS | A, H | |
| 3875 | PHYLLANTHUS EMBLICA | A, E, H | When used as an excipient, only for use in topical medicines for dermal application. |
| 3876 | PHYLLOSTACHYS NIGRA | A, E, H | |
| 3877 | PHYSALIS ALKEKENGI | A, H | |
| 3878 | PHYSALIS PUBESCENS | A, H | |
| 3879 | PHYTANTRIOL | E | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than |

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| | | | 0.5%. |
| 3880 | PHYTOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3881 | PHYTOLACCA AMERICANA | A, H | The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb. |
| 3882 | PHYTOMENADIONE | A, E | |
| 3883 | PHYTOSPHINGOSINE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%. |
| 3884 | PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%. |
| 3885 | PICEA ABIES | A, H | |
| 3886 | PICEA MARIANA | A, H | |
| 3887 | PICRASMA EXCELSA | A, E, H | |
| 3888 | PICRORRHIZA KURROA | A, E, H | |
| 3889 | PIGMENT BLUE 15 | E | Permitted for use only as a colour for topical and dental use.<br>The concentration in medicine must be no more than 0.003%. |
| 3890 | PIGMENT BLUE 15:1 | E | Permitted for use only as a |

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| | | | colour for topical use.<br>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.21%. |
| 3891 | PIGMENT GREEN 7 | E | Permitted for use only as a colour for topical and dental use.<br>When for dental use, the concentration in the medicine must be no more than 0.003%.<br>When for topical use, the concentration in the medicine must be no more than 0.17%. |
| 3892 | PIGMENT RED 4 | E | Permitted for use only as a colour for topical use. |
| 3893 | PIGMENT RED 53 | E | Permitted for use only as a colour for topical use. |
| 3894 | PIGMENT RED 57 | E | Permitted for use only as a colour for topical use. |
| 3895 | PIGMENT RED 57 ALUMINIUM LAKE | E | Permitted for use only as a colour for topical use. |
| 3896 | PIGMENT RED 57 BARIUM LAKE | E | Permitted for excipient use as a colour in topical medicines for dermal application.<br>Not to be included in medicines intended for use in the eye. |
| 3897 | PIGMENT RED 63 | E | Permitted for use only as a colour for topical use. |
| 3898 | PIGMENT WHITE 26 | E | Permitted for use only as a colour for topical use. |

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| 3899 | PIGMENT YELLOW 12 | E | Permitted for use only as a colour for topical use. |
| 3900 | PILOCARPUS JABORANDI | A, H | Pilocarpine is a mandatory component of Pilocarpus jaborandi.<br>The concentration of pilocarpine in the medicine must be no more than 0.025%. |
| 3901 | PILOCARPUS MICROPHYLLUS | A, H | Pilocarpine is a mandatory component of Pilocarpus microphyllus.<br>The concentration of pilocarpine in the medicine must be no more than 0.025%. |
| 3902 | PILOCARPUS PINNATIFOLIUS | A, H | Pilocarpine is a mandatory component of Pilocarpus pinnatifolius.<br>The concentration of pilocarpine in the medicine must be no more than 0.025%. |
| 3903 | PIMENTA FRUIT OIL | A, E, H | |
| 3904 | PIMENTA LEAF OIL | A, E, H | |
| 3905 | PIMENTA OFFICINALIS | A, E, H | |
| 3906 | PIMENTA RACEMOSA | A, E, H | When the plant preparation for Pimenta racemosa is an oil and the concentration of this oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.<br>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.<br>When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, |

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| | | | 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.<br>The medicine requires the following warning statements on the medicine label:<br>- (CHILD) 'Keep out of reach of children' (or word to that effect)<br>- (NTAKEN) 'Not to be taken'. |
| 3907 | PIMPINELLA ANISUM | A, E, H | When the plant preparation for Pimpinella anisum is an oil or distillate and the concentration of this oil or distillate in the medicine is more than 50%:<br>a) the nominal capacity of the container must be no more than 50 millilitres; and<br>b) a restricted flow insert is must be fitted on the container; and<br>c) the medicine requires the following warning statement on the medicine label:<br>- (CHILD) ‘Keep out of reach of children’ (or words to that effect). |
| 3908 | PIMPINELLA SAXIFRAGA | A, E, H | |
| 3909 | PINE NEEDLE OIL SCOTCH | A, E, H | |
| 3910 | PINE NEEDLE OIL TERPENELESS | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 3911 | PINE OIL AROMATIC | A, E, H | |
| 3912 | PINE OIL PUMILIO | A, E, H | |
| 3913 | PINEAPPLE | E | |
| 3914 | PINEAPPLE OILS | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3915 | PINELLIA TERNATA | A, H | |
| 3916 | PINUS CONTORTA | A, E, H | |
| 3917 | PINUS ELLIOTTII | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3918 | PINUS MASSONIANA | A, E, H | When the plant preparation is oil or distillate the total concentration of Pinus massoniana oil or distillate in the preparation must be no more than 25%. |
| 3919 | PINUS MONTICOLA | A, E, H | |
| 3920 | PINUS MUGO | A, E, H | |
| 3921 | PINUS PALUSTRIS | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3922 | PINUS PINASTER | A, E, H | When the plant preparation is |

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| | | | oil or distillate the total concentration of Pinus pinaster oil or distillate in the preparation must be no more than 25%. |
| 3923 | PINUS PONDEROSA | A, E, H | |
| 3924 | PINUS RADIATA | A, E, H | |
| 3925 | PINUS STROBUS | A, E, H | |
| 3926 | PINUS SYLVESTRIS | A, E, H | |
| 3927 | PINUS TABULIFORMIS | A, E, H | |
| 3928 | PINUS YUNNANENSIS | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3929 | PIPENZOLATE BROMIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3930 | PIPER CHABA | A, E, H | |
| 3931 | PIPER CUBEBA | A, E, H | |
| 3932 | PIPER KADSURA | A, E, H | |
| 3933 | PIPER LONGUM | A, E, H | |
| 3934 | PIPER METHYSTICUM | A, H | Kavalactones (of Piper methysticum) is a mandatory component of Piper methysticum.<br>Only for oral use when the dosage form is 'tablet' or 'capsule'; or when the container type is 'tea bag'.<br>When used in oral medicines, the maximum daily dose of kavalactones (of Piper methysticum) must be no more than 250 mg. |

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| | | | 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.<br>Oral medicines containing more than 25 mg of kavalactones (of Piper methysticum) per dose require the following warning statement on the medicine label:<br>- (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'.<br>The plant part must be root or rhizome.<br>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.<br>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.<br>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. |
| 3935 | PIPER NIGRUM | A, E, H | |
| 3936 | PIPER SARMENTOSUM | A, E, H | |
| 3937 | PIPERINE | E | Permitted for use only in combination with other permitted ingredients as a flavour proprietary formulation. |

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| | | | 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%. |
| 3938 | PIPERITONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 3939 | PIPERONAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 3940 | PIPERONYL ACETONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3941 | PIPERONYL BUTOXIDE | E | Only for use in topical medicines for dermal application.<br>The medicine requires the following warning statement on the medicine label: |

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| | | | - (PIPBUT) 'Contains piperonyl butoxide' (or words to that effect). |
| 3942 | 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.<br>The concentration in the medicine must be no more than 1% in wash-on/wash-off medicines and 0.5% in leave-on medicines. |
| 3943 | PISCIDIA PISCIPULA | A, E, H | |
| 3944 | PISTACIA LENTISCUS | A, E, H | |
| 3945 | PISUM SATIVUM | A, E, H | |
| 3946 | PLACENTA | H | Only for use as an active homoeopathic ingredient. |
| 3947 | PLANTAGO AFRA | A, E, H | When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). |
| 3948 | PLANTAGO ARENARIA | A, H | When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). |
| 3949 | PLANTAGO ASIATICA | A, H | When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be |

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| | | | used for children on medical advice' (or words to that effect). |
| 3950 | PLANTAGO LANCEOLATA | A, E, H | The medicine requires the following warning statement on the medicine label:<br>- (CHILD5) 'Use in children under 3 years is not recommended'<br>When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). |
| 3951 | PLANTAGO MAJOR | A, E, H | When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). |
| 3952 | PLANTAGO OVATA | A, H | When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). |
| 3953 | PLANTAGO SEED DRY | A, H | When a dose for children is stated and the plant part is flower, seed or pollen, the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that |

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| | | | effect). |
| 3954 | PLATANUS OCCIDENTALIS | A, E, H | |
| 3955 | PLATANUS RACEMOSA | A, H | |
| 3956 | PLATANUS × HISPANICA | A, H | |
| 3957 | PLATYCODON GRANDIFLORUS | A, E, H | |
| 3958 | PLECTRANTHUS BARBATUS | A, E, H | |
| 3959 | PLICATONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3960 | PLUM | E | |
| 3961 | PLUMBAGO EUROPAEA | A, H | |
| 3962 | PLUMERIA ALBA | A, E, H | |
| 3963 | PLUMERIA RUBRA | A, E, H | |
| 3964 | POA NEMORALIS | A, H | |
| 3965 | POA PRATENSIS | A, H | |
| 3966 | PODOPHYLLUM PELTATUM | A, H | Podophyllin and podophyllotoxin are mandatory components of Podophyllum peltatum.<br>The concentration of podophyllin in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.<br>The concentration of podophyllotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. |
| 3967 | POGOSTEMON CABLIN | A, E, H | |
| 3968 | POLACRILIN | E | |
| 3969 | POLACRILIN POTASSIUM | E | |
| 3970 | POLAPREZINC | A | Only for use in oral medicines.<br>Zinc is a mandatory component of Polaprezinc.<br>The maximum recommended daily dose must be no more |

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| | | | than 34 milligrams of zinc sourced from polaprezinc.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>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:<br>- (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). |
| 3971 | POLIGLUSAM | A, E | The average molecular mass of poliglusam must be greater than 2 kilodaltons.<br>When for internal use:<br>(a) the maximum recommended daily dose of the medicine must not provide more than 1750 milligrams poliglusam; and<br>(b) the following warning statement is required on the medicine label:<br>- (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).<br>When for internal use and the dosage form is a powdered preparation, the following warning statement is required on the medicine label:<br>- (DNTPOW) 'Do not take powder alone. Mix with food or fluid'.<br>When used as an excipient, |

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| | | | only for use in topical medicines for dermal application. |
| 3972 | POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER | A, E | When for oral use:<br>(a) the maximum recommended daily dose of the medicine must not provide more than 2000 mg of Poliglusam derived from Aspergillus niger;<br>(b) the following warning statement (or words to the same effect) is required on the medicine label:<br>- (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication.'; and<br>(c) if the medicine is a powdered dosage form, the following warning statement is also required on the medicine label:<br>- (DNTPOW) 'Do not take powder alone. Mix with food or fluid.'<br>When used as an excipient, Poliglusam derived from Aspergillus niger is only permitted for use in topical medicines for dermal application. |
| 3973 | POLLACK-LIVER OIL | A, E | Colecalciferol and Vitamin A are mandatory components of Pollack-liver oil.<br>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.<br>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.<br>When preparations for internal use in adults contain more than |

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| | | | 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:<br>- (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.<br>- (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.<br>- (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.'<br>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D. |
| 3974 | POLLEN | E | The medicine requires the following warning statement on the medicine label:<br>- (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect). |
| 3975 | POLOXAMER | E | Only for use in topical medicines for dermal application. |
| 3976 | POLOXAMINE | E | Permitted for use only in |

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| | | | combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3977 | POLOXAMINE 1301 | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 3978 | 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.<br>The concentration in the medicine must be no more than 2%. |
| 3979 | POLYACRYLAMIDE | E | Only for use in topical medicines for dermal application.<br>Acrylamide is a mandatory component of Polyacrylamide.<br>The concentration of Acrylamide in the medicine must be no more than 0.01%. |
| 3980 | 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.<br>The concentration in the medicine must be no more than 2%. |
| 3981 | POLYACRYLATE-1 CROSSPOLYMER | E | Only for use in topical medicines for dermal |

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| | | | application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 0.4%. |
| 3982 | POLYACRYLIC ACID | E | |
| 3983 | POLYAMINO SUGAR CONDENSATE | E | Only for use in topical medicines for dermal application. |
| 3984 | 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.<br>The concentration in the medicine must be no more than 0.3%. |
| 3985 | POLYBUTADIENE | E | Only for use as part of an adhesive in topical medicines for dermal application. |
| 3986 | POLYBUTENE | E | Only for use in topical medicines for dermal application. |
| 3987 | POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 2%. |
| 3988 | POLYCAPROLACTONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%. |

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| 3989 | POLYDECENE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 6%. |
| 3990 | POLYDEXTROSE | E | |
| 3991 | POLYDIETHYLSILOXANE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 5%. |
| 3992 | POLYDIMETHYL SILOXANE | E | Permitted for use only in combination with other permitted ingredients as a printing ink.<br>If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1% |
| 3993 | POLYESTER-10 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 1.5%. |
| 3994 | POLYESTER-25 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than |

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| | | | 10%. |
| 3995 | POLYESTER-7 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 3996 | POLYESTER-8 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration of Polyester-8 must be no more than 5%. |
| 3997 | POLYETHYLENE | E | |
| 3998 | POLYGALA CHINENSIS | A, H | |
| 3999 | POLYGALA SENEGA | A, E, H | Except when used in a medicine containing only homoeopathic preparations, a child resistant closure and restricted flow insert must be fitted onto the container. |
| 4000 | POLYGALA SIBIRICA | A, E, H | Only for use when the plant part is root or root bark. |
| 4001 | POLYGALA TENUIFOLIA | A | Only for use when the plant part is root or root bark. |
| 4002 | POLYGLYCERYL-10 PENTASTEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 1.5%. |
| 4003 | POLYGLYCERYL-2 CAPRATE | E | Only for use in topical medicines for dermal application and not to be |

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| | | | included in medicines intended for use on damaged skin or in the eye.<br>The concentration in the medicine must not be more than 0.5%. |
| 4004 | POLYGLYCERYL-2 DIISOSTEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 3.0%. |
| 4005 | POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE | E | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 5%. |
| 4006 | POLYGLYCERYL-2 DISTEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 3%. |
| 4007 | POLYGLYCERYL-2 TRIISOSTEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>When the concentration of polyglyceryl-2 triisostearate is greater than 3%, the medicine must not be intended for use on damaged skin.<br>The concentration in the medicine must not be more than 5%. |
| 4008 | POLYGLYCERYL-2-PEG-4 | E | Only for use in topical |

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| | STEARATE | | medicines for dermal application. |
| 4009 | POLYGLYCERYL-3 BEESWAX | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 0.5%. |
| 4010 | POLYGLYCERYL-3 DIISOSTEARATE | E | Only for use in topical medicines for dermal application. |
| 4011 | POLYGLYCERYL-3 DISTEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.5%. |
| 4012 | POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 6%. |
| 4013 | POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5.5%. |
| 4014 | POLYGLYCERYL-3 POLYRICINOLEATE | E | |
| 4015 | POLYGLYCERYL-3 | E | Only for use in topical |

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| | STEARATE/ISOSTEARATE/DIMER DILINOLEATE CROSSPOLYMER | | medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 5%. |
| 4016 | 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.<br>The concentration in the medicine must be no more than 3%. |
| 4017 | 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.<br>The concentration in the medicine must be no more than 5%. |
| 4018 | POLYGLYCERYL-4 OLEATE | E | Only for use in topical medicines for dermal application. |
| 4019 | POLYGLYCERYL-6 POLYRICINOLEATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 1%. |
| 4020 | POLYGLYCERYL-6 RICINOLEATE | E | Only for use in topical medicines for dermal application. |
| 4021 | POLYGONATUM MULTIFLORUM | A, H | |
| 4022 | POLYGONATUM OFFICINALE | A, H | |

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| 4023 | POLYGONATUM SIBIRICUM | A, E, H | |
| 4024 | POLYGONUM AVICULARE | A, E, H | When used as an excipient, the medicine is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye.<br>When used as an excipient, the concentration in the medicine must be no more than 0.16%. |
| 4025 | POLYGONUM BISTORTA | A, H | |
| 4026 | POLYGONUM ODORATUM | A, H | |
| 4027 | POLYHYDROXYSTEARIC ACID | E | Only for use in topical medicines for dermal application. |
| 4028 | POLYISOBUTYLENE | E | Only for use when the dosage form is 'chewing gum'.<br>Must comply with:<br>a) the Polyisobutylene monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia National Formulary, as in force or existing from time to time. |
| 4029 | POLYISOPRENE | E | Only for use in topical medicines for dermal application. |
| 4030 | POLYLIMONENE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

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| 4031 | POLYMETHACRYLIC ACID | E | |
| 4032 | POLYMETHYL METHACRYLATE | E | Only for use in topical medicines for dermal application. |
| 4033 | POLYMETHYLSILSESQUIOXANE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 3%. |
| 4034 | POLYPORUS UMBELLATUS | A, H | |
| 4035 | POLYPROPYLENE | E | Only for use in topical medicines for dermal application. |
| 4036 | POLYPROPYLENE GLYCOL | E | Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.<br>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.<br>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 4037 | POLYQUATERNIUM-10 | E | Only for use in topical medicines for dermal application. |
| 4038 | POLYQUATERNIUM-11 | E | Only for use in topical medicines for dermal application. |
| 4039 | POLYQUATERNIUM-22 | E | Only for use in wash-off |

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| | | | topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 2%. |
| 4040 | POLYQUATERNIUM-24 | E | Only for use in topical medicines for dermal application. |
| 4041 | POLYQUATERNIUM-28 | E | Only for use in topical medicines for dermal application. |
| 4042 | POLYQUATERNIUM-37 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 2.5%. |
| 4043 | POLYQUATERNIUM-4 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 0.4%. |
| 4044 | POLYQUATERNIUM-44 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.3%. |
| 4045 | POLYQUATERNIUM-51 | E | Only for use in topical medicines for dermal application and not to be |

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

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| 4050 | POLYSILICONE-2 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.13%. |
| 4051 | POLYSORBATE 20 | E | |
| 4052 | POLYSORBATE 40 | E | |
| 4053 | POLYSORBATE 60 | E | |
| 4054 | POLYSORBATE 65 | E | |
| 4055 | POLYSORBATE 80 | E | |
| 4056 | POLYSORBATE 85 | E | Only for use in topical medicines for dermal application. |
| 4057 | POLYSTYRENE | E | Only for use as part of an adhesive in topical medicines for dermal application. |
| 4058 | POLYTEF | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.5%. |
| 4059 | 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.<br>The concentration in the medicine must be no more than 2% in spray applications and 6% in non-spray applications. |
| 4060 | POLYURETHANE-62 | E | Only for use in topical medicines for dermal application and not to be |

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| | | | included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%. |
| 4061 | POLYVINYL ACETATE | E | Only permitted for use in medicines that are for oral routes of administration. |
| 4062 | POLYVINYL ACETATE PHTHALATE | E | |
| 4063 | POLYVINYL ALCOHOL | E | |
| 4064 | POLYVINYL CHLORIDE | E | Only for use in topical medicines for dermal application. |
| 4065 | POMEGRANATE | E | |
| 4066 | PONCEAU SX | E | Permitted for use only as a colour for topical use. |
| 4067 | PONCIRUS TRIFOLIATA | A, H | When used internally, oxedrine is a mandatory component of Poncirus trifoliata.<br>The quantity of Oxedrine in the maximum recommended daily dose must be no more than 30 mg. |
| 4068 | PONGAMOL | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 1%. |
| 4069 | PONTEDERIA CRASSIPES | A, H | |
| 4070 | POPPY SEED | E, H | |
| 4071 | POPPY SEED OIL | E, H | |
| 4072 | POPULUS ALBA | A, H | |
| 4073 | POPULUS BALSAMIIFERA | A, E, H | |
| 4074 | POPULUS CANDICANS | A, H | |
| 4075 | POPULUS DELTOIDES | A, H | |

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| 4076 | POPULUS NIGRA | A, H | |
| 4077 | POPULUS TREMULA | A, H | |
| 4078 | POPULUS TREMULOIDES | A, H | |
| 4079 | PORCINE | H | Only for use as an active homoeopathic ingredient. |
| 4080 | 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.<br>The concentration in the medicine must be no more than 0.5%. |
| 4081 | PORTULACA OLERACEA | A, E, H | |
| 4082 | POTABLE WATER | E | |
| 4083 | POTASSIUM ACETATE | E | |
| 4084 | POTASSIUM ARSENITE | H | Only for use as an active homoeopathic ingredient. |
| 4085 | POTASSIUM ASCORBATE | A, E, H | When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate. |
| 4086 | POTASSIUM ASCORBATE DIHYDRATE | A, E, H | When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate. |
| 4087 | POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE | E | Only for use in topical medicines for dermal application. |
| 4088 | 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. |
| 4089 | POTASSIUM ASPARTATE DIHYDRATE | A, E, H | If used as an active ingredient and the preparation is intended as a mineral supplementation, |

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| | | | 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. |
| 4090 | 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. |
| 4091 | POTASSIUM BICARBONATE | E | |
| 4092 | POTASSIUM BROMIDE | H | Only for use as an active homoeopathic ingredient. |
| 4093 | 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.<br>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. |
| 4094 | POTASSIUM CETYL PHOSPHATE | E | Only for use in topical medicines for dermal application. |
| 4095 | POTASSIUM CHLORIDE | A, E, H | When for oral use:<br>(a) potassium is a mandatory component of potassium chloride;<br>(b) the medicine requires the following warning statement on the medicine label:<br>- (POTAS1) 'If you have |

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| | | | kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and<br>(c) except when the medicine is for use as oral rehydration therapy, the amount of potassium chloride per dosage unit must not be more than 550 mg.<br>Medicines containing potassium chloride for use as oral rehydration therapy, are subject to the following conditions:<br>(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;<br>(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<br>(c) the following warning statements are required on the medicine label:<br>- (UOAD) 'Use only as directed'<br>- (DIAR3) 'If diarrhoea persists, seek medical advice.'<br>When for dental use, the concentration of potassium chloride in the medicine must not be more than 3.75%. |
| 4096 | POTASSIUM CITRATE | A, E, H | When used as an active |

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| | | | ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium citrate. |
| 4097 | 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.<br>The concentration in the medicine must be no more than 10%. |
| 4098 | 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.<br>The concentration in the medicine must be no more than 0.15%. |
| 4099 | POTASSIUM DICHROMATE | H | Only for use as an active homoeopathic ingredient. |
| 4100 | POTASSIUM GLUCONATE | A, E, H | When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium gluconate. |
| 4101 | 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. |
| 4102 | POTASSIUM HYDROXIDE | E | The concentration in the medicine must be no more than 5%.<br>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be |

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| | | | more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. |
| 4103 | POTASSIUM HYDROXYCITRATE | A, H | |
| 4104 | POTASSIUM IODATE | A, H | Iodine is a mandatory component of potassium iodate.<br>The percentage of iodine from potassium iodate should be calculated based on the molecular weight of potassium iodate.<br>When for use in adults, the medicine must contain a daily dose of no more than 505 micrograms of potassium iodate.<br>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. |
| 4105 | POTASSIUM IODIDE | A, E, H | Iodine is a mandatory component of potassium iodide.<br>The percentage of iodine from potassium iodide should be calculated based on the molecular weight of potassium iodide.<br>When for internal use, the maximum recommended daily dose of the medicine must contains less than 300 micrograms of iodine.<br>When for external use, the concentration of iodine in the medicine (excluding salts derivatives or iodophors) must not exceed 2.5%. |
| 4106 | POTASSIUM METABISULFITE | E | Permitted for use only in combination with other permitted ingredients as a |

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| | | | flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4107 | 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.<br>The concentration in the medicine must be no more than 0.5%. |
| 4108 | POTASSIUM NITRATE | A, H | Only for dental use.<br>The concentration in the medicine must be no more than 5%. |
| 4109 | 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.<br>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. |
| 4110 | POTASSIUM PYROPHOSPHATE | E | Only for oral application, dental or topical use.<br>Not to be included in topical medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 3%. |
| 4111 | POTASSIUM SORBATE | E | |
| 4112 | POTASSIUM STANNATE | E | Permitted for use only in combination with other |

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| | | | permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4113 | POTASSIUM STEARATE | E | Only for use in topical medicines for dermal application. |
| 4114 | 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.<br>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. |
| 4115 | POTATO STARCH | E | |
| 4116 | POTENTILLA ANSERINA | A, H | |
| 4117 | POTENTILLA CHINENSIS | A, H | |
| 4118 | POTENTILLA DISCOLOR | A, H | |
| 4119 | POTENTILLA ERECTA | A, E, H | |
| 4120 | POTENTILLA REPTANS | A, H | |
| 4121 | POTERIUM OFFICINALE | A, E, H | |
| 4122 | POTERIUM SANGUISORBA | A, H | |
| 4123 | POVIDONE | E | |
| 4124 | POWDERED CELLULOSE | E | |
| 4125 | 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.<br>The concentration in the medicine must be no more than 5%. |

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| 4126 | 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.<br>The concentration in the medicine must be no more than 2%. |
| 4127 | 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.<br>The concentration in the medicine must be no more than 4%. |
| 4128 | 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.<br>The concentration in the medicine must be no more than 1.4%. |
| 4129 | 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.<br>The concentration of PPG-17/IPDI/DMPA Copolymer in the medicine must be no more than 10%. |
| 4130 | PPG-2 LANOLIN ALCOHOL ETHER | E | Only for use in topical medicines for dermal application. |
| 4131 | 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. |

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| | | | The concentration in the medicine must be no more than 5%. |
| 4132 | PPG-20 LANOLIN ALCOHOL ETHER | E | Only for use in topical medicines for dermal application. |
| 4133 | PPG-20 METHYL GLUCOSE ETHER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.5%. |
| 4134 | PPG-20 METHYL GLUCOSE ETHER DISTEARATE | E | Only for use in topical medicines for dermal application. |
| 4135 | 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.<br>The concentration in the medicine must be no more than 6%. |
| 4136 | PPG-3 MYRISTYL ETHER | E | Only for use in topical medicines for dermal application. |
| 4137 | PPG-5-CETETH-20 | E | Only for use in topical medicines for dermal application. |
| 4138 | PPG-5-LAUROMACROGOL 250 | E | Only for use in topical medicines for dermal application. |
| 4139 | PRALINE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. |

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| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4140 | PREGELATINISED MAIZE STARCH | E | |
| 4141 | PREGELATINISED POTATO STARCH | E | |
| 4142 | PREGELATINISED RICE STARCH | E | |
| 4143 | PREGELATINISED STARCH | E | |
| 4144 | PREGELATINISED WHEAT STARCH | E | When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch. |
| 4145 | PRENYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4146 | PRICKLY ASH BARK DRY | A, H | |
| 4147 | PRICKLY ASH BARK POWDER | A, H | |
| 4148 | PRIMULA VERIS | A, E, H | |
| 4149 | PRIMULA VULGARIS | A, E, H | |
| 4150 | PRINSEPIA UNIFLORA | A, H | |
| 4151 | PROBOSCIDEA PARVIFLORA | A, H | |
| 4152 | PROGESTERONE | H | Only for use as an active homoeopathic ingredient. |
| 4153 | PROLINE | A, E | |
| 4154 | PROPAN-1-OL | E | Only for use in:<br>- topical medicines for dermal application; or<br>- in combination with other permitted ingredients as a |

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| | | | flavour proprietary excipient formulation.<br>The concentration of propan-1-ol in the medicine must not be more than 18%.<br>When used in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation, the total flavour proprietary excipient formulation in a medicine must not be more than 5%. |
| 4155 | PROPANE | E | Only for use as an excipient propellant ingredient. |
| 4156 | 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.<br>The concentration in the medicine must be no more than 10%. |
| 4157 | PROPENYL GUAETHOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4158 | PROPIONALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total |

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| | | | fragrance concentration in a medicine must be no more 1%. |
| 4159 | PROPIONIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4160 | PROPIONYLLEVOCARNITINE HYDROCHLORIDE | A, H | |
| 4161 | PROPOLIS | A, E | Lead is a mandatory component of Propolis.<br>The concentration of lead in the medicine must be no more than 0.001%.<br>When used topically, the medicine requires the following warning statement on the medicine label:<br>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'<br>When used for other than for topical, the medicine requires the following warning statement on the medicine label:<br>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.' |
| 4162 | PROPOLIS BALSAM | A, E | Lead is a mandatory component of Propolis balsam.<br>The concentration of lead in the medicine must be no more than 0.001%.<br>When used topically, the medicine requires the |

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

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| | | | following warning statement on the medicine label:<br>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'<br>When used for other than for topical, the medicine requires the following warning statement on the medicine label:<br>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.' |
| 4165 | PROPOLIS RESIN | A, E | Lead is a mandatory component of propolis resin.<br>The concentration of lead in the medicine must be no more than 0.001%.<br>When used topically, the medicine requires the following warning statement on the medicine label:<br>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'<br>When used for other than for topical, the medicine requires the following warning statement on the medicine label:<br>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.' |
| 4166 | PROPOLIS TINCTURE | A, E | Lead is a mandatory component of Propolis tincture.<br>The concentration of lead in the medicine must be no more than 0.001%.<br>When used topically, the medicine requires the following warning statement on the medicine label: |

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| | | | -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'<br>When used for other than for topical, the medicine requires the following warning statement on the medicine label:<br>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.' |
| 4167 | PROPYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4168 | PROPYL CAPROATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4169 | PROPYL GALLATE | E | |
| 4170 | PROPYL HYDROXYBENZOATE | E | |
| 4171 | PROPYLENE CARBONATE | E | Only for use in topical medicines for dermal application. |
| 4172 | PROPYLENE GLYCOL | E | |
| 4173 | PROPYLENE GLYCOL ALGINATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

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| 4174 | 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.<br>The concentration in the medicine must be no more than 20%. |
| 4175 | 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.<br>The concentration in the medicine must be no more than 1%. |
| 4176 | PROPYLENE GLYCOL DIOCTANOATE | E | Only for use in topical medicines for dermal application. |
| 4177 | PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE | E | Only for use in topical medicines for dermal application. |
| 4178 | PROPYLENE GLYCOL DIPELARGONATE | E | Only for use in topical medicines for dermal application. |
| 4179 | 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.<br>The concentration in the medicine must be no more than 1%. |
| 4180 | PROPYLENE GLYCOL ISOSTEARATE | E | Only for use in topical medicines for dermal application. |
| 4181 | PROPYLENE GLYCOL MONOLAURATE | E | Only for use in topical medicines for dermal |

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| | | | application. |
| 4182 | PROPYLENE GLYCOL MONOSTEARATE | E | Only for use in topical medicines for dermal application. |
| 4183 | PROPYLENE GLYCOL MYRISTYL ETHER ACETATE | E | Only for use in topical medicines for dermal application. |
| 4184 | PROSOPIS JULIFLORA | A, H | |
| 4185 | PROTEASE | A | Must be derived from Aspergillus oryzae or Aspergillus niger. |
| 4186 | PROTEIN HYDROLYSATE | E | |
| 4187 | PRUNE JUICE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4188 | PRUNE JUICE CONCENTRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4189 | PRUNELLA VULGARIS | A, H | |
| 4190 | PRUNUS AFRICANA | A, E, H | Amygdalin and hydrocyanic acid are mandatory components of Prunus africana.<br>The concentration of Amygdalin in the medicine must be 0%.<br>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |

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| 4191 | PRUNUS ARMENIACA | A, E, H | Amygdalin and hydrocyanic acid are mandatory components of Prunus armeniaca and must be declared in the application.<br>The concentration of Amygdalin in the medicine must be 0%.<br>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |
| 4192 | PRUNUS AVIUM | A, E, H | Amygdalin and hydrocyanic acid are mandatory components of Prunus avium.<br>The concentration of Amygdalin in the medicine must be 0%.<br>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |
| 4193 | PRUNUS CERASIFERA | A, E, H | Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera.<br>The concentration of Amygdalin in the medicine must be 0%.<br>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |
| 4194 | PRUNUS CERASUS | A, E, H | Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasus.<br>The concentration of Amygdalin in the medicine must be 0%.<br>The concentration of |

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| | | | Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |
| 4195 | PRUNUS DOMESTICA | A, E, H | Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica.<br>The concentration of Amygdalin in the medicine must be 0%.<br>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |
| 4196 | PRUNUS DULCIS | A, E, H | Amygdalin and hydrocyanic acid are mandatory components of Prunus dulcis when the plant part is seed.<br>When the plant part is seed, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry seed.<br>The concentration of Amygdalin in the medicine must be 0%.<br>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |
| 4197 | PRUNUS HUMILIS | A, E, H | Amygdalin and hydrocyanic acid are mandatory components of Prunus humilis.<br>The concentration of Amygdalin in the medicine must be 0%.<br>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%. |

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

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

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| | | | part is leaf. |
| 4210 | PSIDIUM GUAJAVA | A, E, H | |
| 4211 | PSORINUM | H | Only for use as an active homoeopathic ingredient. |
| 4212 | PSYLLIUM HUSK DRY | A, H | When a dose for children is stated, the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). |
| 4213 | PSYLLIUM HUSK POWDER | A, E, H | When a dose for children is stated, the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). |
| 4214 | PSYLLIUM SEED DRY | A, E, H | When a dose for children is stated the following warning statement is required on the label:<br>- (PSYLL1) 'Should only be used for children on medical advice' (or words to that effect). |
| 4215 | PTELEA TRIFOLIATA | A, H | |
| 4216 | PTEROCARPUS MARSUPIUM | A, H | |
| 4217 | PTEROCARPUS SANTALINUS | A, E, H | |
| 4218 | PUERARIA LOBATA | A, E, H | |
| 4219 | PUERARIA MONTANA VAR. LOBATA | A, E, H | |
| 4220 | PULLULAN | E | |
| 4221 | PUMICE | E | |
| 4222 | PUMPKIN | E | |
| 4223 | PUMPKIN SEED | E, H | |
| 4224 | PUMPKIN SEED OIL | E, H | |

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| 4225 | PUNICA GRANATUM | A, E, H | |
| 4226 | PURE BEE VENOM | H | Only for use as an active homoeopathic ingredient. |
| 4227 | PURIFIED HONEY | A, E | When the route of administration is oral, the following warning statement is required on the medicine label:<br>- (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). |
| 4228 | PURIFIED SILICEOUS EARTH | E, H | |
| 4229 | PURIFIED TALC | E | |
| 4230 | PURIFIED WATER | E | |
| 4231 | PVM/MA COPOLYMER | E | |
| 4232 | PVM/MA DECADIENE CROSSPOLYMER | E | Only for use in topical medicines for dermal application. |
| 4233 | PVP/EICOSENE COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 4234 | PVP/HEXADECENE COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 4235 | PYRETHRINS | E | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 10%.<br>The medicine requires the following warning statement on the medicine label:<br>- (PYRTH3) 'Contains pyrethrins [insert quantity]' (or words to that effect). |
| 4236 | PYRIDOXAL 5-PHOSPHATE | A, E | Pyridoxine is a mandatory component of Pyridoxal 5-phosphate. |

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| | | | The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate.<br>The maximum recommended daily dose must provide no more than 200 mg of pyridoxine.<br>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:<br>- (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].' |
| 4237 | PYRIDOXAL 5-PHOSPHATE MONOHYDRATE | A | Pyridoxine is a mandatory component of Pyridoxal 5-phosphate monohydrate.<br>The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate.<br>The maximum recommended daily dose must provide no more than 200 mg of pyridoxine.<br>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:<br>- (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as |

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| | | | soon as possible. [Contains vitamin B6].' |
| 4238 | PYRIDOXINE HYDROCHLORIDE | A, E, H | When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of Pyridoxine hydrochloride.<br>The percentage of pyridoxine from pyridoxine hydrochloride should be calculated based on the molecular weight of pyridoxine hydrochloride.<br>The maximum recommended daily dose must provide no more than 200 mg of pyridoxine.<br>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:<br>- (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].' |
| 4239 | PYROGLUTAMIC ACID | E | |
| 4240 | PYROLA DECORATA | A, H | |
| 4241 | PYROLIGNEOUS ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4242 | PYRROSIA LINGUA | A, H | |
| 4243 | PYRROSIA PETIOLOSA | A, H | |
| 4244 | PYRROSIA SHEARERI | A, H | |
| 4245 | PYRUS COMMUNIS | A, E, H | Beta-arbutin is a mandatory |

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| | | | component of Pyrus communis.<br>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.<br>When for dermal application exclusively to the face:<br>a) the concentration of beta-arbutin in the medicine must not be more than 7%;<br>b) hydroquinone is a mandatory component; and<br>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.<br>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |
| 4246 | PYRUS PYRIFOLIA | A, H | Beta-arbutin is a mandatory component of Pyrus pyrifolia.<br>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.<br>When for dermal application exclusively to the face:<br>a) the concentration of beta-arbutin in the medicine must not be more than 7%;<br>b) hydroquinone is a mandatory component; and<br>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.<br>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |

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| 4247 | PYRUVIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4248 | QUASSIA | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4249 | QUASSIA AMARA | A, E, H | |
| 4250 | QUASSIA WOOD JAMAICAN DRY | A, H | |
| 4251 | QUASSIA WOOD JAMAICAN POWDER | A, H | |
| 4252 | QUATERNIUM-15 | E | Only for use in topical medicines for dermal application. |
| 4253 | QUATERNIUM-18 BENTONITE | E | Only for use in topical medicines for dermal application. |
| 4254 | QUATERNIUM-18 HECTORITE | E | Only for use in topical medicines for dermal application. |
| 4255 | QUATERNIUM-52 | E | Only for use in wash-on/wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 1%.<br>Not be used in medicines in which N-nitroso compounds may be formed. |

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| 4256 | QUATERNIUM-80 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 2.5%. |
| 4257 | QUERCETIN | A | |
| 4258 | QUERCETIN DIHYDRATE | A | |
| 4259 | QUERCUS ACUTISSIMA | A, H | |
| 4260 | QUERCUS ALBA | A, E, H | |
| 4261 | QUERCUS PALUSTRIS | A, H | |
| 4262 | QUERCUS ROBUR | A, H | |
| 4263 | QUERCUS RUBRA | A, H | |
| 4264 | QUERCUS VIRGINIANA | A, H | |
| 4265 | QUILLAIA DRY | A, H | |
| 4266 | QUILLAIA POWDER | A, E, H | |
| 4267 | QUILLAJA SAPONARIA | A, H | |
| 4268 | QUINCE | E | |
| 4269 | QUININE ARSENITE | H | Only for use as an active homoeopathic ingredient.<br>Quinine is a mandatory component of Quinine arsenite.<br>The maximum recommended daily dose must be no more than 50 mg of quinine. |
| 4270 | QUININE SULFATE DIHYDRATE | H | Only for use as an active homoeopathic ingredient.<br>Quinine is a mandatory component of quinine sulfate dihydrate.<br>The maximum recommended daily dose must be no more than 50 mg of quinine. |
| 4271 | QUINOLINE YELLOW | E | Permitted for use only as a colour for oral and topical use. |
| 4272 | QUINOLINE YELLOW ALUMINIUM LAKE | E | Permitted for use only as a colour for oral and topical use. |

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| 4273 | QUISQUALIS INDICA | A, H | |
| 4274 | R-ALPHA LIPOIC ACID | A | |
| 4275 | RACEMENTHOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4276 | RACEMIC CAMPHOR | E, H | Only for use as an active homoeopathic or excipient ingredient.<br>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.<br>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.<br>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:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br>- (NTAKEN) 'Not to be taken'.<br>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 |

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| | | | have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br>- (NTAKEN) 'Not to be taken'.<br>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:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br>- (NTAKEN) 'Not to be taken'.<br>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres. |
| 4277 | RADISH | E | |
| 4278 | RAISIN JUICE CONCENTRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4279 | RANUNCULUS BULBOSUS | A, H | |
| 4280 | RANUNCULUS FICARIA | A, H | |
| 4281 | RANUNCULUS TERNATUS | A, H | |
| 4282 | RAPE SEED OIL | A, E, H | Allyl isothiocyanate is a mandatory component of rape seed oil when the plant part is |

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| | | | seed.<br>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%. |
| 4283 | RAPHANUS SATIVUS | A, H | |
| 4284 | RASPBERRY | E | |
| 4285 | RASPBERRY BRANDY | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4286 | RASPBERRY DISTILLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4287 | RASPBERRY FRUIT EXTRACT | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4288 | RASPBERRY JUICE CONCENTRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4289 | RAUWOLFIA SERPENTINA | A, H | The concentration of equivalent dry Rauwolfia |

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| | | | serpentina in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 4290 | RAUWOLFIA SERPENTINA DRY | A, H | The concentration of Rauwolfia Serpentina Dry in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 4291 | RAUWOLFIA SERPENTINA POWDER | A, H | The concentration of Rauwolfia Serpentina Powder in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 4292 | RED 27 | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration.<br>The concentration in the medicine must be no more than 0.5%. |
| 4293 | RED 27 ALUMINIUM LAKE | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration.<br>The concentration in the medicine must be no more than 0.5%. |
| 4294 | RED ANT | H | Only for use as an active homoeopathic ingredient. |
| 4295 | RED CLOVER FLOWER DRY | A, H | |
| 4296 | RED CLOVER FLOWER POWDER | A, H | |
| 4297 | RED CORAL | H | Only for use as an active homoeopathic ingredient. |
| 4298 | RED DEER | A | |
| 4299 | RED MERCURIC IODIDE | H | Only for use as an active homoeopathic ingredient. |
| 4300 | RED MERCURIC OXIDE | H | Only for use as an active homoeopathic ingredient. |

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| 4301 | RED MERCURIC SULFIDE | H | Only for use as an active homoeopathic ingredient. |
| 4302 | REHMANNIA GLUTINOSA | A, E, H | |
| 4303 | REL-1-((1R,2S)-1,2,3,4,5,6,7,8-OCTAHYDRO-1,2,8,8-TETRAMETHYL-2-NAPHTHALENYL)-1-ETHANONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4304 | RESORCINOL | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4305 | RESORCINOL DIMETHYLETHER | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4306 | RESVERATROL | A | Only permitted for use in medicines that are for oral routes of administration.<br>The maximum recommended daily dose of the medicine must not contain more than 150 milligrams of resveratrol.<br>The following warning statements are required on the medicine label:<br>- (RESVER) 'Resveratrol may affect the way some medicines work, including Warfarin. Consult your health professional before taking with |

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| | | | other medicines (or words to that effect).';<br>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)'; and<br>- (CHILD2) 'Not suitable for children'. |
| 4307 | RETINOL | A, E | Vitamin A is a mandatory component of retinol.<br>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.<br>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.<br>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:<br>- (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.<br>- (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.<br>- (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents |

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| | | | for women and 900 micrograms retinol equivalents for men.' |
| 4308 | RETINOL ACETATE | A, E | Vitamin A is a mandatory component of retinol acetate.<br>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.<br>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.<br>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:<br>- (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.<br>- (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.<br>- (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.' |
| 4309 | RETINOL PALMITATE | A, E | Vitamin A is a mandatory |

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| | | | component of retinol palmitate.<br>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.<br>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.<br>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:<br>- (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.<br>- (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.<br>- (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.' |
| 4310 | REYNOUTRIA JAPONICA | A, E, H | When used as an excipient, only for use in topical medicines for dermal application. |
| 4311 | RHAMNOSE | E | Permitted for use only in |

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| | | | combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4312 | RHAMNUS CATHARTICA | A, H | When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product |

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| | | | contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4313 | RHAMNUS FRANGULA | A, H | Glucofrangulins calculated as glucofrangulin A is a mandatory component of Rhamnus frangula.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that |

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| | | | effect).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4314 | RHATANY ROOT DRY | A, H | |
| 4315 | RHATANY ROOT POWDER | A, H | |
| 4316 | RHEUM OFFICINALE | A, E, H | The plant part must not be leaf.<br>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum officinale.<br>When used in oral medicines, if the maximum recommended |

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

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| | | | under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4317 | RHEUM PALMATUM | A, E, H | The plant part must not be leaf.<br>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum palmatum.<br>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:<br>- (CHILD3) ‘Use in children under 12 years is not recommended’;<br>- (LAX2) ‘Prolonged use may cause serious bowel problems’; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) ‘Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements |

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| | | | on the medicine label:<br>- (LAX5) ‘This product contains [name of the herb(s) or the chemical component(s)]’; and<br>- (LAX4) ‘This product may have laxative effect’.<br>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:<br>- (CHILD3) ‘Use in children under 12 years is not recommended’;<br>- (LAX1) ‘Drink plenty of water' (or words to that effect); and<br>- (LAX2) ‘Prolonged use may cause serious bowel problems’. |
| 4318 | RHEUM RHAPONTICUM | A, E, H | The plant part must not be leaf.<br>When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rheum rhaponticum.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you |

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| | | | 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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4319 | RHEUM TANGUTICUM | A, H | The plant part must not be leaf.<br>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum tanguticum. |

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| | 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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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 |

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| | | | on the medicine label:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4320 | RHODAMINE B | E | Permitted for use only as a colour for topical use. |
| 4321 | RHODINOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4322 | RHODINYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4323 | RHODIOLA ROSEA | A | Only for use in oral medicines.<br>Only available for use when the plant preparation is dry root powder, dry root powder as an aqueous extract or dry root powder as a hydroethanolic extract with no more than 70% ethanol v/v. |
| 4324 | RHODODENDRON AUREUM | A, H | |
| 4325 | RHODODENDRON FERRUGINEUM | A, H | Beta-arbutin is a mandatory component of Rhododendron ferrugineum. |

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| | | | When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.<br>When for dermal application exclusively to the face:<br>a) the concentration of beta-arbutin in the medicine must not be more than 7%;<br>b) hydroquinone is a mandatory component; and<br>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.<br>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |
| 4326 | RHODODENDRON GROENLANDICUM | A, H | |
| 4327 | RHODODENDRON MOLLE | A, H | The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material. |
| 4328 | RHUBARB | E, H | When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhubarb.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and |

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| | | | - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4329 | RHUBARB ROOT DRY | A, H | When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a |

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| | mandatory component of rhubarb root dry.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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 |

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| | | | medicine requires the following warning statements on the medicine label:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4330 | 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.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or |

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| | | | marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4331 | RHUS AROMATICA | A, E, H | |
| 4332 | RHUS CHINENSIS | A, H | |
| 4333 | RHUS GLABRA | A, E, H | |
| 4334 | RHUS VENENATA | H | Only for use as an active homoeopathic ingredient. |
| 4335 | RIBES GROSSULARIA | A, E, H | |
| 4336 | RIBES NIGRUM | A, E, H | |
| 4337 | RIBOFLAVIN | A, E | |
| 4338 | RIBOFLAVIN SODIUM PHOSPHATE | A, E | |
| 4339 | RIBOFLAVIN TETRAACETATE | E | Only for use in topical medicines for dermal application. |
| 4340 | RIBOFLAVINE | A, E | |
| 4341 | RIBOFLAVINE SODIUM PHOSPHATE | A, E | |

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| 4342 | RIBONUCLEIC ACID | E | Only for use in topical medicines for dermal application. |
| 4343 | RIBOSE | A | Only for use in oral medicines. |
| 4344 | RICE | E | |
| 4345 | RICE BRAN | E | |
| 4346 | RICE BRAN OIL | E | |
| 4347 | RICE BRAN WAX | A, E, H | |
| 4348 | RICE STARCH | E | |
| 4349 | RICE VINEGAR | E | |
| 4350 | RICE WINE | E | Ethanol is a mandatory component of rice wine. |
| 4351 | RICINOLEIC ACID | E | Only for use in topical medicines for dermal application. |
| 4352 | RICINUS COMMUNIS | A, H | Only for use when the plant part must be seed and the plant preparation is oil fixed. |
| 4353 | ROBINIA PSEUDOACACIA | A, E, H | When the herbal substance is derived from plant parts other than the leaf or flower, the maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material. |
| 4354 | ROHDEA JAPONICA | A, H | The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 4355 | ROSA ARVENSIS | A, E, H | |
| 4356 | ROSA CANINA | A, E, H | |
| 4357 | ROSA CYMOSA | A, E, H | |
| 4358 | ROSA EGLANTERIA | A, E, H | |
| 4359 | ROSA GALLICA | A, E, H | |
| 4360 | ROSA LAEVIGATA | A, E, H | |
| 4361 | ROSA MULTIFLORA | A, E, H | |

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| 4362 | 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.<br>The concentration in the medicine must be no more than 0.002%. |
| 4363 | ROSA RUGOSA | A, E, H | |
| 4364 | ROSA VILLOSA | A, E, H | |
| 4365 | ROSA X CENTIFOLIA | A, E, H | |
| 4366 | ROSA X DAMASCENA | A, E, H | |
| 4367 | ROSANA | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4368 | ROSE ABSOLUTE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4369 | ROSE FRUIT FRESH | A, E, H | |
| 4370 | ROSE HIP | E | |
| 4371 | ROSE OIL | A, E, H | |
| 4372 | ROSE OXIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total |

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| | | | fragrance concentration in a medicine must be no more 1%. |
| 4373 | ROSEMARY OIL | A, E, H | Safrole is a mandatory component of Rosemary oil.<br>When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.<br>When for topical use then the concentration of safrole in the medicine must be no more than 1%. |
| 4374 | ROSMARINUS OFFICINALIS | A, E, H | Camphor and cineole are mandatory components of Rosmarinus officinalis.<br>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.<br>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.<br>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.<br>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:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br>- (NTAKEN) 'Not to be taken'. |

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| | | | In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br>- (NTAKEN) 'Not to be taken'.<br>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres. |
| 4375 | ROYAL JELLY | A, E | 10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly.<br>The medicine requires the following warning statements on the medicine label:<br>- (CHILD2) 'Not suitable for children'<br>- (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'. |
| 4376 | ROYAL JELLY FRESH | A, E | 10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh.<br>The medicine requires the following warning statements on the medicine label:<br>- (CHILD2) 'Not suitable for children' |

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| | | | - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'. |
| 4377 | ROYAL JELLY LYOPHILISED | A, E | 10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly lyophilised.<br>The medicine requires the following warning statements on the medicine label:<br>- (CHILD2) 'Not suitable for children'<br>- (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'. |
| 4378 | RUBBER NATURAL | E | Only for use in topical medicines for dermal application. |
| 4379 | RUBIA CORDIFOLIA | A, H | |
| 4380 | RUBIA TINCTORUM | A, H | |
| 4381 | RUBUS CHINGII | A, H | |
| 4382 | RUBUS CORCHORIFOLIUS | A, H | |
| 4383 | RUBUS COREANUS | A, E, H | |
| 4384 | RUBUS FRUTICOSUS | A, E, H | |
| 4385 | RUBUS IDAEUS | A, E, H | |
| 4386 | RUBUS OCCIDENTALIS | A, E, H | |
| 4387 | RUBUS PARVIFOLIUS | A, H | |
| 4388 | RUBUS ROSIFOLIUS | A, H | |
| 4389 | RUDBECKIA HIRTA | A, H | |
| 4390 | RUE OIL | A, H | |
| 4391 | RUM | E | Permitted for use only in |

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| | | | combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4392 | RUMEX ACETOSA | A, H | |
| 4393 | RUMEX ACETOSELLA | A, H | |
| 4394 | RUMEX CONGLOMERATUS | A, H | |
| 4395 | RUMEX CRISPUS | A, E, H | |
| 4396 | RUMEX PULCHER | A, H | |
| 4397 | RUMEX SCUTATUS | A, H | |
| 4398 | RUSCUS ACULEATUS | A, H | |
| 4399 | RUTA GRAVEOLENS | A, E, H | |
| 4400 | RUTOSIDE | A, E | |
| 4401 | RYE | E | Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal. |
| 4402 | RYE BRAN | E | Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal. |
| 4403 | S-ISOPROPYL 3-METHYLTHIOCROTONATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4404 | SABINENE | E | Sabinene must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.<br>The total concentration of flavour proprietary excipient formulations containing sabinene must not be more than |

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| | | | 5% of the total medicine. |
| 4405 | SABINENE HYDRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4406 | SACCHARIDE ISOMERATE | E | Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 3.66%. |
| 4407 | SACCHARIN | E | |
| 4408 | SACCHARIN SODIUM | E | |
| 4409 | SACCHAROMYCES CEREVISIAE | A, E | When for topical use, the concentration in the medicine must be no more than 1%. |
| 4410 | SACCHAROMYCES CEREVISIAE (BOULARDII) | A | |
| 4411 | 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.<br>The concentration in the medicine must be no more than 1%. |
| 4412 | SACCHAROMYCES/ZINC FERMENT | E | Only for use in topical medicines for dermal application. |
| 4413 | SACCHARUM OFFICINARUM | A, E, H | |
| 4414 | SAFFLOWER OIL | A, E, H | |
| 4415 | SAFFRON | E | Permitted for use only as a colour for either topical use or with an oral route of |

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| | | | administration. |
| 4416 | SAGE LEAF DRY | A, E, H | Thujone is a mandatory component of Sage leaf dry.<br>The concentration of thujone in the medicine must be no more than 4%. |
| 4417 | SAGE LEAF POWDER | A, H | Thujone is a mandatory component of Sage leaf powder.<br>The concentration of thujone in the medicine must be no more than 4%. |
| 4418 | SAGE OIL DALMATIAN | A | Thujone is a mandatory component of Sage oil dalmatian.<br>The concentration of thujone in the medicine must be no more than 4%.<br>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:<br>- (CHILD) ‘Keep out of reach of children’ (or word to that effect)<br>- (NTAKEN) ‘Not to be taken’ |
| 4419 | SAGE OIL SPANISH | A, E, H | |
| 4420 | 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.<br>The concentration in the medicine must be no more than 0.002%. |

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| 4421 | SALICYLALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4422 | SALICYLIC ACID | E, H | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 40%. |
| 4423 | SALIX ALBA | A, E, H | |
| 4424 | SALIX DAPHNOIDES | A, H | |
| 4425 | SALIX DISCOLOR | A, H | |
| 4426 | SALIX FRAGILIS | A, H | |
| 4427 | SALIX NIGRA | A, H | |
| 4428 | SALIX PURPUREA | A, H | |
| 4429 | SALSOLA KALI | A, H | |
| 4430 | SALVIA CHINENSIS | A, H | |
| 4431 | SALVIA FRUTICOSA | A, H | |
| 4432 | SALVIA HISPANICA | A, E, H | |
| 4433 | SALVIA LAVANDULAEFOLIA | A, H | |
| 4434 | SALVIA MILTIORRHIZA | A, H | |
| 4435 | SALVIA OFFICINALIS | A, E, H | Thujone is a mandatory component of Salvia officinalis.<br>The concentration of thujone in the medicine must be no more than 4%. |
| 4436 | SALVIA SCLAREA | A, E, H | |
| 4437 | SAMBUCUS CANADENSIS | A, H | |
| 4438 | SAMBUCUS EBULUS | A, H | |
| 4439 | SAMBUCUS NIGRA | A, E, H | |
| 4440 | SANDALWOOD OIL EAST | A, E, H | |

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| 4441 | SANGUINARIA CANADENSIS | H | Only for use as an active homoeopathic ingredient.<br>The potency must be more than 4X. |
| 4442 | SANICULA EUROPAEA | A, H | |
| 4443 | SANTALUM ALBUM | A, E, H | |
| 4444 | SANTALUM SPICATUM | A, E, H | The route of administration must be topical or inhalation.<br>The plant preparation must be oil.<br>The plant part must be root or stem wood including heartwood. |
| 4445 | SAPINDUS MUKOROSSI | A, H | |
| 4446 | SAPONARIA OFFICINALIS | A, H | |
| 4447 | SAPOSHNIKOVIA DIVARICATA | A, H | |
| 4448 | SARCOSINE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.5%. |
| 4449 | SARGASSUM FUSIFORME | A, H | Iodine is a mandatory component of Sargassum fusiforme.<br>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.<br>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 4450 | SARGASSUM SILIQUASTRUM | A, H | Iodine is a mandatory component of Sargassum siliquastrum. |

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| | | | Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.<br>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 4451 | SASSAFRAS ALBIDUM | A, H | Safrole is a mandatory component of Sassafras albidum.<br>When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.<br>When for topical use then the concentration of safrole in the medicine must be no more than 1%. |
| 4452 | SATUREIA HORTENSIS | A, H | |
| 4453 | SATUREIA MONTANA | A, H | |
| 4454 | SAUROPUS SPATULIFOLIUS | A, H | |
| 4455 | SAURURUS CHINENSIS | A, H | |
| 4456 | SAUSSUREA COSTUS | A, H | |
| 4457 | SAVORY OIL SUMMER | A, H | |
| 4458 | SAXIFRAGA GRANULATA | A, E, H | |
| 4459 | SAXIFRAGA STOLONIFERA | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 0.0816%. |
| 4460 | SCAPHIUM SCAPHIGERUM | A, H | |
| 4461 | SCHEFFLERA HEPTAPHYLLA | A, H | |
| 4462 | SCHINOPSIS QUEBRACHO-COLORADO | A, H | |
| 4463 | SCHINUS MOLLE | A, H | |
| 4464 | SCHINUS MOLLE OIL | E | Permitted for use only in |

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| | | | combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4465 | SCHISANDRA CHINENSIS | A, E, H | |
| 4466 | SCHIZONEPETA TENUIFOLIA | A, E, H | |
| 4467 | SCHOENOCAULON OFFICINALE | A, H | The maximum recommended daily dose must contain no more than the equivalent of 1mg of the dry herbal material. |
| 4468 | SCLAREOL | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4469 | SCLAREOLIDE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4470 | SCLERANTHUS ANNUUS | A, H | |
| 4471 | SCLEROTIUM GUM | E | Only for use in topical medicines for dermal application. |
| 4472 | 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%. |
| 4473 | SCROPHULARIA NINGPOENSIS | A, H | |
| 4474 | SCROPHULARIA NODOSA | A, H | |

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| 4475 | SCURRULA PARASITICA VAR. GRACILIFLORA | A, H | |
| 4476 | SCUTELLARIA BAICALENSIS | A, E, H | |
| 4477 | SCUTELLARIA BARBATA | A, H | |
| 4478 | SCUTELLARIA LATERIFLORA | A, E, H | |
| 4479 | 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.<br>The concentration in the medicine must be no more than 0.02%. |
| 4480 | SEC BUTYL 3-METHYLBUT-2-ENETHIOATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4481 | SEC-BUTYL THIOISOVALERATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4482 | 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. |
| 4483 | SEDUM ACRE | A, H | |
| 4484 | SELAGINELLA TAMARISCINA | A, H | |
| 4485 | SELENICEREUS GRANDIFLORUS | A, E, H | |
| 4486 | SELENIUM | H | Only for use as an active homoeopathic ingredient.<br>Oral medicines must contain no more than 150 micrograms |

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| | | | of selenium per maximum recommended daily dose.<br>When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (SELE) 'This medicine contains selenium which is toxic in high doses.<br>A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.' |
| 4487 | SELENOCYSTEINE | A | Selenium is a mandatory component of Selenocysteine for oral and sublingual use.<br>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.<br>When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (SELE) 'This medicine contains selenium which is toxic in high doses.<br>A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.' |
| 4488 | SELENOMETHIONINE | A | Selenium is a mandatory component of Selenomethionine for oral and sublingual use.<br>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.<br>When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (SELE) 'This medicine contains selenium which is |

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| | | | toxic in high doses. A daily dose of 150 micograms for adults of selenium from dietary supplements should not be exceeded.' |
| 4489 | SELF-EMULSIFYING GLYCERYL MONOSTEARATE | E | |
| 4490 | 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. |
| 4491 | SEMOLINA | E | |
| 4492 | SEMPERVIVUM TECTORUM | A, H | |
| 4493 | SENEGA ROOT DRY | A, H | |
| 4494 | SENEGA ROOT POWDER | A, H | |
| 4495 | SENNA ALEXANDRINA | A, H | When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna alexandrina.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as |

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| | | | a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4496 | 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.<br>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: |

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| | | - (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may |

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| | | | cause serious bowel problems'. |
| 4497 | 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.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'. |

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| | | | 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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4498 | 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.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine |

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| | | | requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4499 | 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.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not |

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| | | recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |

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| 4500 | 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.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]';<br>- (LAX4) 'This product may have laxative effect'.<br>When used in oral medicines, if the maximum recommended daily dose contains less than 10 |

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| | | | mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4501 | 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.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: |

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| | | | - (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4502 | 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.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended'; |

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| | | - (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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].<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' [or words to that effect].<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended;<br>- (LAX1) 'Drink plenty of water' [or words to that effect]; and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |

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| 4503 | SENNA TORA | A, H | When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna tora.<br>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:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX2) 'Prolonged use may cause serious bowel problems'; and<br>- (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).<br>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:<br>- (LAX1) 'Drink plenty of water' (or words to that effect).<br>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and<br>- (LAX4) 'This product may have laxative effect'.<br>When used in oral medicines, if the maximum recommended daily dose contains less than 10 |

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| | | | mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:<br>- (CHILD3) 'Use in children under 12 years is not recommended';<br>- (LAX1) 'Drink plenty of water' (or words to that effect); and<br>- (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 4504 | SEPIA | H | Only for use as an active homoeopathic ingredient. |
| 4505 | SEQUOIA SEMPERVIRENS | A, H | |
| 4506 | SEQUOIADENDRON GIGANTEUM | A, H | |
| 4507 | SERENOA REPENS | A, H | |
| 4508 | SERINE | A, E | |
| 4509 | SERUM ANGUILLAE | H | Only for use as an active homoeopathic ingredient. |
| 4510 | SESAME OIL | A, E, H | |
| 4511 | SESAME SEED | E | |
| 4512 | SESAMUM INDICUM | A, E, H | |
| 4513 | SETARIA ITALICA | A, H | |
| 4514 | SHARK CALCIUM CHONDROITIN SULFATE | A | |
| 4515 | SHARK CARTILAGE | A, E | The medicine requires the following warning statement on the medicine label:<br>- (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) |
| 4516 | SHARK CHONDROITIN SULFATE | A, E | When used as an excipient:<br>- only for use in topical |

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| | | | medicines for dermal application;<br>- not to be included in medicines intended for use in the eye; and<br>- the concentration in the medicine must be no more than 0.001%. |
| 4517 | SHARK POTASSIUM CHONDROITIN SULFATE | A | |
| 4518 | SHARK SODIUM CHONDROITIN SULFATE | A, E | When used as an excipient:<br>- only for use in topical medicines for dermal application;<br>- not to be included in medicines intended for use in the eye; and<br>- the concentration in the medicine must be no more than 0.001%. |
| 4519 | SHARK-LIVER OIL | A, E | Vitamin A and Colecalciferol are mandatory components of Shark-liver oil.<br>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.<br>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.<br>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.<br>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:<br>- (VITA2) ‘WARNING: If you |

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

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| | | | flavour concentration in a medicine must be no more than 5%. |
| 4528 | 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.<br>The concentration in the medicine must be no more than 4%. |
| 4529 | SILICA SILYLATE | E | Only for use in topical medicines for dermal application. |
| 4530 | SILICIFIED MICROCRYSTALLINE CELLULOSE | E | Only for use when the route of administration is other than inhalation. |
| 4531 | SILICON DIOXIDE | A, E, H | Only for use when the route of administration is other than inhalation. |
| 4532 | 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.<br>The concentration in the medicine must be no more than 2.5%.<br>The medicine requires the following warning statement on the medicine label:<br>- (EYE) 'Avoid contact with eyes' (or words to that effect). |
| 4533 | SILVER | H | Only for use as an active homoeopathic ingredient.<br>The concentration in the medicine must be no more than 1%. |
| 4534 | SILVER BEET | E, H | |

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| 4535 | 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.<br>The concentration in the medicine should be no more than 0.6%.<br>Silver is a mandatory component of Silver borosilicate when the route of administration is topical.<br>The concentration of silver in the medicine must be no more than 1%. |
| 4536 | SILVER NITRATE | H | Only for use as an active homoeopathic ingredient. |
| 4537 | SILYBUM MARIANUM | A, E, H | |
| 4538 | SIMABA CEDRON | A, H | |
| 4539 | SIMETHICONE | E | |
| 4540 | SIMMONDSIA CHINENSIS | A, E, H | |
| 4541 | SINAPIS ALBA | A, H | Allyl isothiocyanate is a mandatory component of Sinapis alba when the plant part is seed.<br>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%. |
| 4542 | SINAPIS ARVENSIS | A, H | |
| 4543 | SINOMENIUM ACUTUM | A, H | |
| 4544 | SIPHONESTEGIA CHINENSIS | A, H | |
| 4545 | SIRAITIA GROSVENORII | A, E, H | |
| 4546 | SISYMBRIUM OFFICINALE | A, H | |
| 4547 | SKATOLE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than |

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| | | | 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4548 | SKIPJACK-LIVER OIL | A, E | Vitamin A and Colecalciferol are mandatory components of Skipjack-liver oil.<br>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.<br>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.<br>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.<br>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:<br>- (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.<br>- (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.<br>- (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 |

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| | | | micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' |
| 4549 | SLIPPERY ELM BARK DRY | A, H | |
| 4550 | SLIPPERY ELM BARK POWDER | A, E, H | |
| 4551 | SMILAX ARISTOLOCHIIFOLIA | A, H | |
| 4552 | SMILAX CHINA | A, H | |
| 4553 | SMILAX GLABRA | A, H | |
| 4554 | SMILAX OFFICINALIS | A, E, H | |
| 4555 | SMILAX ORNATA | A, E, H | |
| 4556 | SMOKE EXTRACT | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4557 | SODIUM ACETATE | E | |
| 4558 | 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.<br>The concentration in the medicine must be no more than 1%. |
| 4559 | SODIUM ACID CITRATE | A, E, H | When sodium acid citrate is used as an active ingredient, only for use in oral medicines. |
| 4560 | 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.<br>The concentration in the medicine must be no more than 0.8%. |
| 4561 | SODIUM ACRYLATES | E | Only for use in topical |

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| | CROSSPOLYMER-2 | | medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 0.7 % (w/w). |
| 4562 | SODIUM ACRYLOYDIMETHYLTAURATE/ VP CROSSPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 2% (w/w). |
| 4563 | SODIUM ALGINATE | E | |
| 4564 | SODIUM ASCORBATE | A, E, H | |
| 4565 | 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.<br>When used in a sunscreen, the concentration in the medicine must be no more than 0.1%.<br>When used in products other than sunscreens, the concentration in the medicine must be no more than 0.5%. |
| 4566 | 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.<br>The concentration in the medicine must be no more than 5%. |
| 4567 | SODIUM BENZOATE | E | |
| 4568 | SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE | A, H | |
| 4569 | SODIUM BETA-HYDROXY- | A, H | |

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| | BETA-METHYLBUTYRATE MONOHYDRATE | | |
| 4570 | SODIUM BICARBONATE | A, E | When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms.<br>Medicines containing sodium bicarbonate for use as oral rehydration therapy are subject to the following conditions:<br>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;<br>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.'<br>c) the following warning statements are required on the medicine label:<br>- (UOAD) 'Use only as directed.'<br>- (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).'<br>- (DIAR3) 'If diarrhoea persists, seek medical advice.' |
| 4571 | SODIUM BISULFITE | E | |

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| 4572 | SODIUM BROMIDE | H | Only for use as an active homoeopathic ingredient. |
| 4573 | SODIUM BUTYRATE | A, E | The route of administration for medicines that contain sodium butyrate must be limited to oral.<br>The maximum recommended daily dose of the medicine must not provide more than 1200 mg sodium butyrate.<br>The following warning statement (or words to the same effect) is required on the medicine label:<br>- (ADULT) 'Adults only'. |
| 4574 | SODIUM C14-16 OLEFIN SULFONATE | E | Only for use in topical medicines for dermal application. |
| 4575 | SODIUM CALCIUM EDETATE | E | When for oral use, sodium is a mandatory component of sodium calcium edetate.<br>Sodium calcium edetate must only be included in medicines when:<br>(a) the route of administration is limited to topical for dermal use; or<br>(b) in combination with other permitted ingredients as a flavour proprietary excipient formulation.<br>The total concentration of sodium calcium edetate in the medicine must not exceed 0.32%.<br>The total concentration of flavour proprietary excipient formulations containing sodium calcium edetate must not be more than 5% of the total medicine. |
| 4576 | SODIUM CARBOMER | E | Only for use as an excipient in topical medicines for dermal |

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| | | | application. |
| 4577 | SODIUM CARBONATE | E | |
| 4578 | SODIUM CARBONATE MONOHYDRATE | E | |
| 4579 | SODIUM CARBOXYMETHYL BETAGLUCAN | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.005%. |
| 4580 | SODIUM CARRAGEENAN | E | |
| 4581 | SODIUM CASEINATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4582 | SODIUM CETOSTEARYL SULFATE | E | Only for use in topical medicines for dermal application. |
| 4583 | SODIUM CHLORIDE | A, E, H | |
| 4584 | SODIUM CHONDROITIN SULFATE | A, E | When used as an excipient ingredient:<br>a) only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye;<br>b) the concentration in the medicine must not be more than 0.001%.<br>When used as an active ingredient:<br>a) the route of administration must only be oral; |

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| | | | b) the maximum daily dose must not provide more than 1,200 mg of sodium chondroitin sulfate;<br>c) the following statements must be included on the medicine label:<br>- (ADULT) 'Adults only' (or words to that effect);<br>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect). |
| 4585 | SODIUM CITRATE | A, E | When for use as an active ingredient, only for oral use. |
| 4586 | SODIUM CITRATE DIHYDRATE | A, E | When for use as an active ingredient, only for oral use. |
| 4587 | 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.<br>The concentration in the medicine must be no more than 0.05%. |
| 4588 | SODIUM COCOAMPHOACETATE | E | Only for use in topical medicines for dermal application. |
| 4589 | SODIUM COCOYL SARCOSINATE | E | Only for use in topical medicines for dermal application. |
| 4590 | SODIUM CYCLAMATE | E | |
| 4591 | SODIUM DEHYDROACETATE | E | Only for use in topical medicines for dermal application. |
| 4592 | SODIUM DNA | E | Only for use in topical medicines for dermal application and not to be included in medicines intended |

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| | | | for use in the eye.<br>The concentration in the medicine must be no more than 0.1%. |
| 4593 | SODIUM DODECYLBENZENESULFONATE | E | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 30%. |
| 4594 | SODIUM ERYTHORBATE | E | |
| 4595 | SODIUM ETHYL HYDROXYBENZOATE | E | |
| 4596 | SODIUM FLUORIDE | A, E, H | Fluoride is a mandatory component of sodium fluoride.<br>The route of administration must be limited to dental.<br>The dosage form must be limited to pastes, powders and/or gels for dental hygiene.<br>When used as an active ingredient, the medicine is subject to the following conditions:<br>(a) only for use in combination with at least one other active ingredient; and<br>(b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg.<br>When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label:<br>- (DNTSW) 'Do not swallow.'<br>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.' |
| 4597 | SODIUM FUMARATE | E | |
| 4598 | SODIUM HYALURONATE | A, E | When for use as an excipient |

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| | | | ingredient, sodium hyaluronate must only be used in medicines with a topical route of administration for dermal application.<br>When for use as an active ingredient:<br>(a) the molecular mass of sodium hyaluronate must be between 600 and 1600 kilodaltons; and<br>(b) sodium hyaluronate must only be used in medicines when the route of administration is limited to:<br>(i) topical for dermal application; or<br>(ii) oral.<br>When for use in a topical medicine for dermal application the concentration of sodium hyaluronate in the medicine must not exceed 2.0%.<br>When for use as an active ingredient and the route of administration is oral:<br>(a) the maximum recommended daily dose must not provide more than 200 milligrams sodium hyaluronate;<br>(b) the recommended duration of use of the medicine must be limited to three months; and<br>(c) the following warning statements (or words to the same effect) are required on the medicine label :<br>- (ADULT) 'Adults only'; and<br>- (PREGNT) ' Not recommended for use by pregnant and lactating women'. |
| 4599 | SODIUM HYDROGENATED TALLOW GLUTAMATE | E | Only for use in topical medicines for dermal application. |

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| 4600 | SODIUM HYDROXIDE | E | The concentration of sodium hydroxide in the medicine must not be more than 5%.<br>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. |
| 4601 | SODIUM HYDROXYCITRATE | A | |
| 4602 | 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.<br>The concentration in the medicine must be no more than 1.5%. |
| 4603 | SODIUM HYDROXYMETHYLGLYCINATE | E | Only for use in topical medicines for dermal application. |
| 4604 | SODIUM HYPOCHLORITE | E | Chlorine is a mandatory component of sodium hypochlorite.<br>The concentration of chlorine in the medicine must not be more than 4%. |
| 4605 | SODIUM ISOSTEAROYL LACTYLATE | E | Only for use in topical medicines for dermal application. |
| 4606 | SODIUM LACTATE | E | |
| 4607 | SODIUM LAURETH SULFATE | E | |
| 4608 | 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.<br>The concentration in the medicine must be no more than |

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| | | | 5%. |
| 4609 | 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.<br>The concentration in the medicine must be no more than 11%. |
| 4610 | SODIUM LAUROYL SARCOSINATE | E | Only for use in topical medicines for dermal application. |
| 4611 | SODIUM LAURYL PHOSPHATE | E | |
| 4612 | SODIUM LAURYL SULFATE | E | |
| 4613 | SODIUM LAURYL SULFOACETATE | E | Only for use in topical medicines for dermal application. |
| 4614 | SODIUM MAGNESIUM SILICATE | E | Only for use in topical medicines for dermal application. |
| 4615 | 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.<br>The concentration in the medicine must be no more than 0.5%. |
| 4616 | SODIUM METABISULFITE | E | |
| 4617 | 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.<br>The concentration in the medicine must not be more than 0.1%. |

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| 4618 | SODIUM METHYL COCOYL TAURATE | E | Only for dental use.<br>The concentration in the medicine must be no more than 2%. |
| 4619 | SODIUM METHYL HYDROXYBENZOATE | E | |
| 4620 | SODIUM MOLYBDATE DIHYDRATE | A | Only for use in oral medicines.<br>Molybdenum is a mandatory component of Sodium molybdate dihydrate.<br>The percentage of molybdenum from sodium molybdate dihydrate should be calculated based on the molecular weight of sodium molybdate dihydrate.<br>The maximum daily dose of molybdenum from Sodium molybdate dihydrate must be no more than 125 micrograms. |
| 4621 | SODIUM MONOFLUOROPHOSPHATE | A | Fluoride is a mandatory component of sodium monofluorophosphate.<br>The route of administration must be limited to dental.<br>The dosage form must be limited to pastes, powders and/or gels for dental hygiene.<br>When sodium monofluorophosphate is used as an active ingredient, it is subject to the following conditions:<br>(a) only for use in combination with at least one other active ingredient; and<br>(b) the concentration of fluoride ion in the medicine must not be more than 1,500 mg/kg.<br>When the concentration of fluoride ion is more than 1000 mg/kg, the following warning statements are required on the medicine label: |

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| | | | - (DNTSW) 'Do not swallow.'<br>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.' |
| 4622 | 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.<br>The concentration in the medicine must be no more than 0.0164%. |
| 4623 | SODIUM NITRATE | H | Only for use as an active homoeopathic ingredient. |
| 4624 | SODIUM NONOXYNOL-4 SULFATE | E | Only for use in topical medicines for dermal application. |
| 4625 | SODIUM PANTOTHENATE | A, E, H | |
| 4626 | SODIUM PCA | E | Only for use in topical medicines for dermal application. |
| 4627 | SODIUM PERBORATE | A, H | Boron is a mandatory component of sodium perborate.<br>When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron.<br>When used in preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron from all ingredients in the product must not exceed 3500 mg/kg or 3500 mg/L or 0.35%.<br>When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the |

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| | | | following warning statements is required on the label:<br>- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or<br>- (ADULT) 'Adults only' (or words to that effect).<br>When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:<br>- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or<br>- (ADULT) 'Adults only' (or words to that effect).<br>When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:<br>- (BORON) 'Contains boron' (or words to that effect).<br>When the medicine is for topical use for dermal application, the following warning statement is required on the label:<br>- (BROKEN) 'Use on unbroken skin only' (or words to that effect). |
| 4628 | SODIUM PERCARBONATE | E | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 15%. |

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| 4629 | SODIUM POLYACRYLATE | E | Only for use in topical medicines for dermal application. |
| 4630 | SODIUM POLYACRYLATE STARCH | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 1%. |
| 4631 | SODIUM POLYMETAPHOSPHATE | E | |
| 4632 | SODIUM PROPIONATE | E | |
| 4633 | SODIUM PROPYL HYDROXYBENZOATE | E | |
| 4634 | 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.<br>The concentration in the medicine must be no more than 0.2%. |
| 4635 | SODIUM SELENATE | A, H | Selenium is a mandatory component of sodium selenate.<br>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.<br>When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (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.' |
| 4636 | SODIUM SELENATE | A | Selenium is a mandatory |

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| | DECAHYDRATE | | component of sodium selenate decahydrate.<br>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.<br>When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (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.' |
| 4637 | SODIUM SELENITE | A, H | Selenium is a mandatory component of Sodium selenite.<br>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.<br>When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (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.’ |
| 4638 | SODIUM SELENITE PENTAHYDRATE | A | Selenium is a mandatory component of Sodium selenite pentahydrate.<br>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.<br>When for oral use, the medicine requires the following warning statement on the medicine label:<br>- (SELE) 'This medicine |

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| | | | 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.' |
| 4639 | SODIUM SILICATE | E | |
| 4640 | SODIUM STARCH GLYCOLLATE | E | |
| 4641 | SODIUM STARCH GLYCOLLATE TYPE A | E | |
| 4642 | SODIUM STEARATE | E | Only for use in topical medicines for dermal application. |
| 4643 | 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.<br>The concentration in the medicine must be no more than 2%. |
| 4644 | 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.<br>The concentration in the medicine must be no more than 2.5%. |
| 4645 | SODIUM STEAROYL LACTYLATE | E | Only for use in topical medicines for dermal application. |
| 4646 | 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.<br>The concentration in the medicine must be no more than 1.5%. |
| 4647 | SODIUM SUCCINATE | E | Only for use in topical |

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| | | | medicines for dermal application. |
| 4648 | SODIUM SULFATE | A, E, H | When it is not intended to be a laxative, the following warning statement is required on the medicine label:<br>- (LAX4) 'Substance may have a laxative effect'. |
| 4649 | SODIUM SULFATE DECAHYDRATE | A, E, H | When it is not intended to be a laxative, the following warning statement is required on the medicine label:<br>- (LAX4) 'Substance may have a laxative effect'. |
| 4650 | SODIUM SULFITE | E | |
| 4651 | SODIUM SULFITE HEPTAHYDRATE | E | Only for use in topical medicines for dermal application. |
| 4652 | SODIUM TRIPOLYPHOSPHATE | E | Only for use when the route of administration is topical for dermal application, mucous membrane (buccal mucosa) or dental.<br>Not to be included in topical medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 4653 | SOLANUM DULCAMARA | A, H | When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum dulcamara.<br>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine. |
| 4654 | SOLANUM FEROX | A, H | When for internal use, steroidal alkaloids calculated as solanine |

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| | | | is a mandatory component of Solanum ferox.<br>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine. |
| 4655 | 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.<br>The concentration in the medicine must be no more than 0.02%. |
| 4656 | SOLANUM MELONGENA | A, H | When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum melongena.<br>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine. |
| 4657 | SOLANUM NIGRUM | A, H | When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum nigrum.<br>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine. |
| 4658 | SOLANUM TUBEROSUM | A, H | When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum tuberosum.<br>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal |

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| | | | alkaloids calculated as solanine. |
| 4659 | SOLIDAGO GIGANTEA | A, H | |
| 4660 | SOLIDAGO GIGANTEA MIS | A, E, H | |
| 4661 | SOLIDAGO VIRGAUREA | A, E, H | |
| 4662 | SOLUBLE MAIZE STARCH | E | |
| 4663 | SOLUBLE POTATO STARCH | E | |
| 4664 | SOLVENT GREEN 3 | E | Permitted for use only as a colour for topical use. |
| 4665 | SOLVENT RED 1 | E | Permitted for use only as a colour for topical use. |
| 4666 | SOLVENT VIOLET 13 | E | Permitted for use only as a colour for topical use. |
| 4667 | SOLVENT YELLOW 172 | E | Permitted for use only as a colour for topical use.<br>The concentration in the medicine must be no more than 0.3%. |
| 4668 | SOLVENT YELLOW 33 | E | Permitted for use only as a colour for topical use. |
| 4669 | SOPHORA FLAVESCENS | A, E, H | |
| 4670 | SOPHORA TONKINENSIS | A, H | |
| 4671 | SORBIC ACID | E | |
| 4672 | SORBITAN ISOSTEARATE | E | Only for use in topical medicines for dermal application. |
| 4673 | SORBITAN MONO-OLEATE | E | |
| 4674 | SORBITAN MONOLAURATE | E | |
| 4675 | SORBITAN MONOSTEARATE | E | |
| 4676 | SORBITAN OLEATE | E | |
| 4677 | 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.<br>The concentration in the |

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| | | | medicine must be no more than 10%. |
| 4678 | 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.<br>The concentration in the medicine must be no more than 2%. |
| 4679 | SORBITAN SESQUIISOSTEARATE | E | Only for use in topical medicines for dermal application. |
| 4680 | SORBITAN SESQUIOLEATE | E | Only for use in topical medicines for dermal application. |
| 4681 | SORBITAN STEARATE | E | |
| 4682 | SORBITAN TRISTEARATE | E | Only for use in topical medicines for dermal application. |
| 4683 | 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. |
| 4684 | SORBITOL SOLUTION (70 PER CENT) (CRYSTALLISING) | A, E | Sorbitol is a mandatory component of sorbitol solution (70 per cent) (crystallising).<br>When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the |

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| | | | British Pharmacopoeia, as in force or existing from time to time. |
| 4685 | SORBITOL SOLUTION (70 PER CENT) (NON-CRYSTALLISING) | A, E | Sorbitol is a mandatory component of sorbitol solution (70 per cent) (non-crystallising).<br>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. |
| 4686 | SORBUS AUCUPARIA | A, H | |
| 4687 | SORGHUM | E | |
| 4688 | SORGHUM VULGARE | A, H | |
| 4689 | SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID | A | Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid.<br>The concentration of soy phosphatidylserine in the medicine must be no more than 15%. |
| 4690 | SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER | A | Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder.<br>The concentration of soy phosphatidylserine in the medicine must be no more than 15%. |
| 4691 | SOY POLYSACCHARIDE | E | |
| 4692 | SOY PROTEIN | E | |
| 4693 | SOY STEROL | E | |
| 4694 | SOYA BEAN | E | |
| 4695 | SOYA BRAN | E | |
| 4696 | SOYA OIL | A, E, H | |

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| 4697 | SOYBEAN FLOUR | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4698 | 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.<br>The concentration in the medicine must be no more than 4%. |
| 4699 | SPARGANIUM STOLONIFERUM | A, H | |
| 4700 | SPARTIUM JUNCEUM | A, H | |
| 4701 | SPATHOLOBUS SUBERECTUS | A, H | |
| 4702 | SPEARMINT OIL | A, E, H | Menthol is a mandatory component of spearmint oil.<br>When the medicine is for topical use for dermal application:<br>(i) the medicine must not be intended for use in the eye or on damaged skin;<br>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>(iii) the following warning statement is required on the medicine label:<br>- (EYE) Avoid contact with eyes (or words to that effect).<br>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:<br>- (SKTEST) If you have |

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| | | | sensitive skin, test this product on a small area of skin before applying it to a large area;<br>- (IRRIT) If irritation develops, discontinue use.<br>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:<br>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol. |
| 4703 | SPEARMINT OIL TERPENELESS | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.<br>Menthol is a mandatory component of spearmint oil terpeneless.<br>When the medicine is for topical use for dermal application:<br>i) the medicine must not be intended for use in the eye or on damaged skin;<br>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;<br>iii) the following warning statement is required on the |

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| | | | medicine label:<br>- (EYE) Avoid contact with eyes (or words to that effect).<br>iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:<br>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;<br>- (IRRIT) If irritation develops, discontinue use.<br>v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:<br>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.<br>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol. |
| 4704 | SPHINGOLIPIDS | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%. |
| 4705 | SPIGELIA ANTHELMIA | A, H | |
| 4706 | SPIGELIA MARILANDICA | A, H | The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 4707 | SPIKE LAVENDER OIL | A, E, H | Camphor is a mandatory |

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| | component of spike lavender oil.<br>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.<br>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.<br>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:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br>- (NTAKEN) 'Not to be taken'.<br>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:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br>- (NTAKEN) 'Not to be taken'.<br>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 |

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| | | | closure fitted on the container and include the following warning statements on the medicine label:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br>- (NTAKEN) 'Not to be taken'.<br>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres. |
| 4708 | SPINACH | E | |
| 4709 | SPINACIA OLERACEA | A, E, H | |
| 4710 | SPIRODELA POLYRRHIZA | A, H | |
| 4711 | SPIRULINA | E | |
| 4712 | SPRAY-DRIED GLUCOSE SYRUP | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4713 | SPRAY-DRIED LIQUID GLUCOSE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4714 | SPRUCE OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4715 | SQUALANE | E | Only for use in topical medicines for dermal application. |

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| 4716 | SQUALENE | A, E | |
| 4717 | SQUID OIL | A | Only for use in oral medicines.<br>The medicine requires the following warning statement on the medicine label:<br>- (SFOOD) 'Derived from seafood'.<br>Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in combination with other ingredients in the medicine and be presented in a therapeutic dosage form for therapeutic use. |
| 4718 | SQUILL DRY | A, H | |
| 4719 | SQUILL INDIAN DRY | A, H | |
| 4720 | SQUILL INDIAN POWDER | A, H | |
| 4721 | SQUILL POWDER | A, H | |
| 4722 | ST JOHN'S WORT DRY EXTRACT QUANTIFIED | A | When used for oral ingestion, the medicine requires the following warning statement on the medicine label:<br>- (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.' |
| 4723 | ST JOHN'S WORT HERB DRY | A, H | When used for oral ingestion, the medicine requires the following warning statement on the medicine label:<br>- (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.' |
| 4724 | ST JOHN'S WORT HERB POWDER | A, H | When used for oral ingestion, the medicine requires the following warning statement on the medicine label:<br>- (STJOHN) 'St John's Wort |

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| | | | affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.' |
| 4725 | STACHYS OFFICINALIS | A, E, H | |
| 4726 | STACHYS PALUSTRIS | A, H | |
| 4727 | STACHYURUS HIMALAICUS | A, H | |
| 4728 | 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.<br>The concentration in the medicine must be no more than 0.005%. |
| 4729 | STANNOUS CHLORIDE | H | Only for use as an active homoeopathic ingredient. |
| 4730 | STAR ANISE OIL | A, E | When the concentration in the medicine is more than 50% and the nominal capacity of the container is equal to or less than 50mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect). |
| 4731 | STARCH | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4732 | STARCH SODIUM OCTENYL SUCCINATE | E | |
| 4733 | STEARALKONIUM CHLORIDE | E | Only for use in topical medicines for dermal |

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| 4734 | STEARALKONIUM HECTORITE | E | Only for use in topical medicines for dermal application. |
| 4735 | STEARAMIDE | E | Only for use in topical medicines for dermal application. |
| 4736 | STEARAMIDOETHYL DIETHYLAMINE | E | Only for use in topical medicines for dermal application. |
| 4737 | STEARAMIDOPROPYL DIMETHYLAMINE | E | Only for use in topical medicines for dermal application. |
| 4738 | STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE | E | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 2%.<br>When the medicine is intended to be used on the eye, the medicine requires the following warning statement on the medicine label:<br>- (EYE2) 'May be irritant to the eyes' (or words to that effect). |
| 4739 | STEARETH-10 | E | Only for use in topical medicines for dermal application. |
| 4740 | 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.<br>The concentration in the medicine must be no more than 1.5%. |
| 4741 | STEARETH-2 | E | Only for use in topical |

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| | | | medicines for dermal application. |
| 4742 | STEARETH-20 | E | Only for use in topical medicines for dermal application. |
| 4743 | STEARETH-21 | E | Only for use in topical medicines for dermal application. |
| 4744 | STEARETH-5 | E | Only for use in topical medicines for dermal application. |
| 4745 | STEARIC ACID | E | |
| 4746 | STEAROPTENES | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4747 | 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.<br>The concentration in the medicine must be no more than 4%. |
| 4748 | STEAROXYTRIMETHYLSILANE | E | Only for use in topical medicines for dermal application. |
| 4749 | STEAROYL MACROGOLGLYCERIDES | E | Only for use in oral medicines.<br>The concentration in the medicine must be no more than 0.6%. |
| 4750 | STEARYL ACETATE | E | Only for use in topical medicines for dermal application. |

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| 4751 | STEARYL ALCOHOL | E | |
| 4752 | STEARYL BEHENATE | E | Only for use as an excipient ingredient for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 3.5% in the final formulation. |
| 4753 | 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.<br>The concentration in the medicine must be no more than 4.5%.<br>The medicine requires the following warning statements on the medicine label:<br>- (EYE2) 'May be irritant to the eyes' (or words to that effect)<br>- (EYE) 'Avoid contact with eyes' (or words to that effect). |
| 4754 | STEARYL GLYCYRRHETINATE | E | Only for use in topical medicines for dermal application. |
| 4755 | STEARYL HEPTANOATE | E | Only for use in topical medicines for dermal application. |
| 4756 | STEARYL MYRISTATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4757 | STEARYL STEARATE | E | Only for use in topical |

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| | | | medicines for dermal application. |
| 4758 | STELLARIA CHAMAEJASME | A, H | |
| 4759 | STELLARIA DICHOTOMA | A, H | |
| 4760 | STELLARIA MEDIA | A, E, H | |
| 4761 | STEMONA JAPONICA | A, H | |
| 4762 | STEMONA SESSILIFOLIA | A, H | |
| 4763 | STENOTAPHRUM SECUNDATUM | A, H | |
| 4764 | STEPHANIA TETRANDA | A, H | |
| 4765 | STERCULIA | A, H | |
| 4766 | STERCULIA TRAGACANTHA | A, H | |
| 4767 | STERCULIA URENS | A, H | |
| 4768 | STEVIA REBAUDIANA | A, E, H | |
| 4769 | STEVIOL GLYCOSIDES | E | Only for use in oral medicines. |
| 4770 | STILLINGIA SYLVATICA | A, H | |
| 4771 | STORAX PREPARED | A, E, H | |
| 4772 | STRAWBERRY | E | |
| 4773 | STRAWBERRY ESSENCE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4774 | STREPTOCOCCUS SALIVARIUS | A | Only permitted for use in medicines:<br>- that are for oral routes of administration; and<br>- when the strain of Streptococcus salivarius is confirmed to be K12 or M18.<br>The name of the Streptococcus salivarius strain must be declared on the label.<br>The following warning statement is required on the medicine label:<br>- (CHILD5) 'Use in children under 3 years is not |

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| | | | recommended'. |
| 4775 | STREPTOCOCCUS THERMOPHILUS | A | |
| 4776 | STROBILANTHES CUSIA | A, H | |
| 4777 | STRONG AMMONIA SOLUTION | E | Ammonia is a mandatory component of strong ammonia solution.<br>The concentration of ammonia in the medicine must be no more than 0.5%.<br>When for internal use, the concentration in the medicine must be no more than 0.25%. |
| 4778 | STRONTIUM CARBONATE | H | Only for use as an active homoeopathic ingredient. |
| 4779 | STROPHANTHUS GRATUS | H | Only for use as an active homoeopathic ingredient. |
| 4780 | STROPHANTHUS HISPIDUS | H | Only for use as an active homoeopathic ingredient. |
| 4781 | STRYCHNOS IGNATII | H | Only for use as an active homoeopathic ingredient.<br>Strychnine (of Strychnos spp.) is a mandatory component of Strychnos ignatii.<br>The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%. |
| 4782 | STRYCHNOS NUX-VOMICA | A, H | Strychnine (of Strychnos spp.) is a mandatory component of Strychnos nux-vomica.<br>The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%. |
| 4783 | STYPHNOLOBIUM JAPONICUM | A, E, H | |

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| 4784 | STYRALLYL PROPIONATE | E | Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.<br>The total fragrance proprietary excipient formulation in a medicine must not be more than 1%. |
| 4785 | STYRAX BENZOIN | A, E, H | |
| 4786 | STYRAX OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4787 | STYRAX PARALLELONEURUM | A, H | |
| 4788 | STYRAX TONKINENSIS | A, H | |
| 4789 | STYRENE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4790 | STYRENE/ACRYLATES COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 4791 | STYROLYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 4792 | SUBLIMED SULFUR | H | Only for use as an active homoeopathic ingredient. |
| 4793 | SUCCINIC ACID | E | |
| 4794 | SUCRALOSE | E | |
| 4795 | SUCROSE | E | |
| 4796 | SUCROSE ACETATE ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4797 | 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.<br>The concentration in the medicine must be no more than 0.3%. |
| 4798 | 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.<br>The concentration in the medicine must be no more than 2%. |
| 4799 | SUCROSE DISTEARATE | E | Only for use in topical medicines for dermal application. |
| 4800 | SUCROSE LAURATE | E | When for oral or sublingual use, sucrose is a mandatory component of sucrose laurate. |
| 4801 | SUCROSE OCTAACETATE | E | When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate. |

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| 4802 | SUCROSE PALMITATE | E | Only for use in topical medicines for dermal application. |
| 4803 | 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.<br>The concentration in the medicine must be no more than 1%.<br>The medicine requires the following warning statements on the medicine label:<br>- (EYE) 'Avoid contact with the eyes' (or words to that effect)<br>- (EYE2) 'May be irritant to the eyes' (or words to that effect). |
| 4804 | SUCROSE STEARATE | E | For use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>When for topical use, the concentration in the medicine must be no more than 0.25%.<br>For oral use as a manufacturing aid only.<br>When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit. |
| 4805 | 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.<br>The concentration in the medicine must be no more than 2%. |
| 4806 | SUDAN III | E | Permitted for use only as a colour for topical use. |

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| 4807 | SUGAR CANE WAX ALCOHOLS | A, H | The maximum recommended daily dose must not provide more than 12mg.<br>The medicine requires the following warning statements on the medicine label:<br>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect). |
| 4808 | SUGARCANE | E, H | When for oral or sublingual use, sucrose is a mandatory component of sugarcane. |
| 4809 | SULFATED CASTOR OIL | E | Only for use in topical medicines for dermal application. |
| 4810 | 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.<br>The concentration in the medicine must be no more than 0.025%. |
| 4811 | SULFUR DIOXIDE | E | |
| 4812 | SULFUR IODIDE | H | Only for use as an active homoeopathic ingredient. |
| 4813 | SULFURIC ACID | E, H | Only for use as an active homoeopathic ingredient or excipient ingredient.<br>The concentration in the medicine must be no more than 0.5%. |
| 4814 | SULFURISED 1-METHYL-4-(1-METHYLETHENYL)-CYCLOHEXENE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a |

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| | | | medicine must be no more than 1%. |
| 4815 | 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.<br>The concentration in the medicine must not be more than 10%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 4816 | 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.<br>The concentration in the medicine must not be more than 10%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 4817 | SUNFLOWER OIL | A, E, H | |
| 4818 | SUNFLOWER SEED | E, H | |
| 4819 | SUNSET YELLOW FCF | E | Permitted for use only as a colour for either topical use or |

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| | | | with an oral route of administration. |
| 4820 | SUNSET YELLOW FCF ALUMINIUM LAKE | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 4821 | SUPEROXIDE DISMUTASE | E | Only for use in topical medicines for dermal application. |
| 4822 | SWEDE | E | |
| 4823 | SWEET ORANGE OIL TERPENES AND TERPENOIDS | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4824 | SWEET POTATO | E | |
| 4825 | SWERTIA CHIRATA | A, H | |
| 4826 | SWIETENIA MAHOGANI | A, H | |
| 4827 | SYAGRUS ROMANZOFFIANA | A, E, H | |
| 4828 | SYMPHYOTRICHUM NOVI-BELGII | A, H | |
| 4829 | SYMPHYTUM OFFICINALE | H | When used orally as an active homoeopathic ingredient, the concentration must be a dilution of 12X or more.<br>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%. |
| 4830 | SYMPLOCARPUS FOETIDUS | A, H | |
| 4831 | SYNTHETIC BEESWAX | E | Only for use in topical medicines for dermal applications. |

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| 4832 | SYNTHETIC TERPENE RESIN | E | Only for use in topical, oral or oral application medicines.<br>When the route of administration is oral, the dosage form must be chewing gum. |
| 4833 | SYNTHETIC WAX | E | |
| 4834 | SYRINGA RETICULATA | A, H | |
| 4835 | SYRINGA VULGARIS | A, H | |
| 4836 | 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:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect); and<br>- (NTAKEN) 'Not to be taken'.<br>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.<br>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.<br>When the plant preparation is |

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| | | | 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%. |
| 4837 | SYZYGIUM CUMINI | A, H | |
| 4838 | SYZYGIUM JAMBOS | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 0.0693%. |
| 4839 | TABEBUIA SERRATIFOLIA | A, E, H | |
| 4840 | TAGETES ERECTA | A, E, H | When used as an excipient ingredient, only for use in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%. |
| 4841 | TAGETES MINUTA | A, E, H | |
| 4842 | TAGETES OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4843 | TAIPAN SNAKE | H | Only for use as an active homoeopathic ingredient. |
| 4844 | TALLOW | E | Only for use in topical |

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| | | | medicines for dermal application. |
| 4845 | TALLOW GLYCERIDES | E | |
| 4846 | TAMARINDUS INDICA | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4847 | TAMARIX APHYLLA | A, H | |
| 4848 | TAMARIX CHINENSIS | A, H | |
| 4849 | TAMARIX GALLICA | A, H | |
| 4850 | TAMUS COMMUNIS | A, H | If the plant part is fruit or root, the maximum recommended daily dose must be no more than 1mg of the equivalent dry fruit or dry root of Tamus communis. |
| 4851 | TANACETUM CINERARIIFOLIUM | A, H | The concentration in the medicine must be no more than 10%. |
| 4852 | TANACETUM PARTHENIUM | A, E, H | |
| 4853 | TANACETUM VULGARE | A, H | Oil (of Tanacetum vulgare) is a mandatory component of Tanacetum vulgare.<br>The concentration of oil (of Tanacetum vulgare) in the medicine must be no more than 0.8%. |
| 4854 | TANGERINE OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than |

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| | | | 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4855 | TANGERINE OIL COLDPRESSED | A, E, H | When used internally, oxedrine is a mandatory component of tangerine oil coldpressed.<br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. |
| 4856 | TANNIC ACID | E | |
| 4857 | TAPIOCA STARCH | E | |
| 4858 | TARAXACUM MONGOLICUM | A, E, H | |
| 4859 | TARAXACUM OFFICINALE | A, E, H | |
| 4860 | TARO | E | |
| 4861 | TARRAGON OIL | A, E, H | |
| 4862 | TARTARIC ACID | E | |
| 4863 | TARTRAZINE | E | Only for use as a colour.<br>Only for use in medicines for topical and oral administration. |
| 4864 | TARTRAZINE ALUMINIUM LAKE | E | Only for use as a colour.<br>Only for use in medicines for topical and oral administration. |
| 4865 | TASMANNIA LANCEOLATA | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4866 | TAURINE | A, E | |
| 4867 | TEA-STEARATE | E | Only for use in topical medicines for dermal application. |
| 4868 | TERMINALIA ARJUNA | A | Only for use in oral medicines.<br>Only for use when the plant |

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| | | | part is bark.<br>The maximum recommended daily dose must be no more than 6 grams of Terminalia arjuna dried bark or its extract equivalents.<br>The medicine requires the following warning statements on the medicine label:<br>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)<br>- (CHILD2) 'Not suitable for children'. |
| 4869 | TERMINALIA BELLIRICA | A | Only for use when the preparation is as an aqueous extract of the fruit pericarp. |
| 4870 | TERMINALIA CATAPPA | A, H | |
| 4871 | TERMINALIA CHEBULA | A, H | |
| 4872 | 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.<br>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.<br>When used as an excipient, the concentration in the medicine must be no more than 0.3%. |
| 4873 | 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.<br>Only for use when the plant part is root bark.<br>Only methanol/water (90:10; V/V) extract of Terminalia |

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| | | | sericea bark of the root is approved.<br>The concentration in the medicine must be no more than 0.1%. |
| 4874 | TERPENE RESIN | E | Terpene resin must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient formulation in medicines with a dermal route of administration for topical application. |
| 4875 | TERPINEN-4-OL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4876 | TERPINEOL | E | |
| 4877 | TERPINEOL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4878 | TERPINOLENE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than |

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| | | | 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4879 | TERPINYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4880 | TERPINYL BUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4881 | TERPINYL METHYL ETHER | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4882 | TERT-BUTYL ALCOHOL | E | Only for use in topical medicines for dermal application. |
| 4883 | TERT-BUTYL HYDROQUINONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 4884 | TERT-BUTYL METHYL ETHER | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4885 | TERT-BUTYLPYRAZINE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4886 | TETRACLINIS ARTICULATA | A, E, H | |
| 4887 | 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.<br>The concentration in the medicine must be no more than 0.002%. |
| 4888 | TETRADIUM RUTICARPUM | A, H | When for internal use, oxedrine is a mandatory component of Tetradium ruticarpum.<br>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg. |
| 4889 | 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.<br>The concentration in the medicine must be no more than 1%. |

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| 4890 | TETRAHYDRO LINALYLACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4891 | TETRAHYDRO PARA-METHYLQUINOLINE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4892 | TETRAHYDRO-6-(3-PENTENYL)-2H-PYRAN-2-ONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4893 | TETRAHYDRODIFERULOYLMETHANE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%. |
| 4894 | TETRAHYDROFURFURYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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| 4895 | TETRAHYDROGERANYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4896 | TETRAHYDROLINALOOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4897 | TETRAHYDROMUGUOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4898 | TETRAHYDROMYRCENOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4899 | TETRAHYDROXYPROPYL ETHYLENEDIAMINE | E | Only for use in topical medicines for dermal application. |
| 4900 | TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a |

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| | | | medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4901 | TETRAPANAX PAPYRIFER | A, H | |
| 4902 | TETRASODIUM ETIDRONATE | E | Only for use in topical medicines for dermal application. |
| 4903 | TETRASODIUM PYROPHOSPHATE | E | |
| 4904 | TEUCRIUM CHAMAEDRYS | A, H | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys. |
| 4905 | TEUCRIUM MARUM | A, H | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum. |
| 4906 | TEUCRIUM SCORODONIA | A, H | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia. |
| 4907 | THAPSIA GARGANICA | A, H | |
| 4908 | THAUMATIN | E | |
| 4909 | THEASPIRANE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4910 | THEMEDA TRIANDRA | A, H | |
| 4911 | THEOBROMA CACAO | A, E, H | Caffeine is a mandatory component of Theobroma cacao. |

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

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| | | | When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:<br>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'<br>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect). |
| 4912 | THEOBROMA OIL | A, E, H | |
| 4913 | THIAMINE | A, E | |
| 4914 | THIAMINE HYDROCHLORIDE | A, E | |
| 4915 | THIAMINE NITRATE | A, E | |
| 4916 | THIOCINEOLE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4917 | THIOTAURINE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.02%. |
| 4918 | THLASPI ARVENSE | A, E, H | |
| 4919 | THREONINE | A, E | |
| 4920 | THUJA OCCIDENTALIS | A, H | |
| 4921 | THUJA PLICATA | A, E, H | |
| 4922 | THYME HERB DRY | A, E, H | |

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| 4923 | 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:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect). |
| 4924 | THYMOL | A, E | When used as an active ingredient, the medicine must be medicated space spray or medicated throat lozenges.<br>When used as an excipient, only for use in medicated throat lozenges or topical medicines for dermal applications. |
| 4925 | THYMOL METHYL ETHER | E | Thymol methyl ether must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.<br>The total concentration of the flavour proprietary excipient formulation containing thymol methyl ether must not be more than 5% of the total medicine. |
| 4926 | THYMUS CAPITATUS | A, E, H | When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect). |

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| 4927 | THYMUS GLAND | H | Only for use as an active homoeopathic ingredient. |
| 4928 | 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). |
| 4929 | 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). |
| 4930 | THYMUS VULGARIS | A, E, H | When the plant preparation is oil or distillate, and the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%:<br>(a) the nominal capacity of the container must not be more than 25 millilitres;<br>(b) a restricted flow insert must be fitted on the container; and<br>(c) the following warning statement is required on the medicine label:<br>- (CHILD) 'Keep out of reach of children' (or words to that |

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| | | | effect). |
| 4931 | THYMUS VULGARIS MIS | A, E, H | When the plant preparation is an oil or distillate, and the concentration of Thymus vulgaris MIS oil or distillate in the preparation is greater than 50%:<br>(a) the nominal capacity of the container must not be more than 25 millilitres;<br>(b) a restricted flow insert must be fitted on the container; and<br>(c) the following warning statement is required on the label:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect). |
| 4932 | THYMUS ZYGIS | A, H | When the plant preparation is an oil or a distillate, and the concentration of Thymus zygis oil or distillate in the preparation is greater than 50%:<br>(a) the nominal capacity of the container must not be more than 25 millilitres;<br>(b) a restricted flow insert must be fitted on the container; and<br>(c) the following warning statement is required on the label:<br>- (CHILD) 'Keep out of reach of children' (or words to that effect). |
| 4933 | TIGER SNAKE | H | Only for use as an active homoeopathic ingredient. |
| 4934 | TILACTASE | A | Must be derived from Aspergillus oryzae and comply with the relevant USP monograph. |
| 4935 | TILIA CORDATA | A, E, H | |

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| 4936 | TILIA PLATYPHYLLOS | A, E, H | |
| 4937 | TILIA TOMENTOSA | A, H | |
| 4938 | TILIA X VULGARIS | A, E, H | |
| 4939 | TILIANTOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4940 | TIN | H | Only for use as an active homoeopathic ingredient. |
| 4941 | TINOSPORA CORDIFOLIA | A, H | |
| 4942 | TINOSPORA SINENSIS | A, H | |
| 4943 | TITANIUM DIOXIDE | A, E | For use as an active ingredient only in sunscreens for dermal application.<br>The concentration in sunscreens must be no more than 25%.<br>For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration.<br>Not to be included in medicines intended for use in the eye.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 4944 | TOCOCYSTEAMIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended |

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| | | | for use in the eye.<br>The concentration in the medicine must be no more than 0.01%. |
| 4945 | TOCOFERSOLAN | E | Only for oral and topical use.<br>When for oral use, the concentration in the medicine must be no more than 10% w/w.<br>When used in topical medicines for dermal application, it is not to be included in medicines intended for use in the eye.<br>When for topical use, the concentration in the medicine must be no more than 0.1% |
| 4946 | TOCOPHEROL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4947 | TOCOPHERYL GLUCOSIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye.<br>The concentration in the medicine must be no more than 0.05% |
| 4948 | TOCOPHERYL LINOLEATE | E | Only for use in topical medicines for dermal application. |
| 4949 | TOCOPHERYL NICOTINATE | E | Only for use in topical medicines for dermal |

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| | | | application and not to be included in medicines intended for use in the eye.<br>The concentration must not exceed 0.3%. |
| 4950 | TOLU BALSAM | A, E, H | |
| 4951 | TOLUENE | E | The residual solvent limit for toluene is 8.9 mg per maximum recommended daily dose.<br>The concentration in the medicine must be no more than 0.089%. |
| 4952 | TOLYL ALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4953 | TOLYLALDEHYDE GLYCERYLACETAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4954 | TOMATO | E | |
| 4955 | TONKA | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4956 | TONKA BEAN EXTRACT | E | Permitted for use only in |

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| | | | combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4957 | TONONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4958 | TOXICODENDRON DIVERSILOBUM | H | Only for use as an active homoeopathic ingredient. |
| 4959 | TOXICODENDRON PUBESCENS | H | Only for use as an active homoeopathic ingredient.<br>The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron pubescens. |
| 4960 | TOXICODENDRON RADICANS | A, H | The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans. |
| 4961 | TOXICODENDRON SUCCEDANEUM | H | Only for use as an active homoeopathic ingredient. |
| 4962 | TRACHELOSPERMUM JASMINOIDES | A, E, H | |
| 4963 | TRACHYSPERMUM AMMI | A, E | Only for use in oral medicines when the plant part is fruit or seed.<br>The medicine requires the following warning statements |

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| | | | on the medicine label:<br>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)<br>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect).<br>Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4964 | TRAGACANTH | A, E | |
| 4965 | TRAMETES VERSICOLOR | A, H | |
| 4966 | TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE | A, H | Only for use in oral medicines. |
| 4967 | TRANS,TRANS-2,4-DECADIEN-1-AL | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4968 | TRANS,TRANS-2,4-HEXADIENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.<br>The maximum daily dose must provide no more than 13.5 mg of Trans,Trans-2,4-Hexadienal. |

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| 4969 | 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.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4970 | TRANS-2-DECENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4971 | TRANS-2-DODECENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4972 | TRANS-2-HEPTEN-1-AL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4973 | TRANS-2-HEXENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than |

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| | | | 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4974 | TRANS-2-HEXENOIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4975 | TRANS-2-HEXENOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 4976 | TRANS-2-HEXENYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4977 | TRANS-2-HEXENYL PHENYLACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4978 | TRANS-2-HYDROXYCINNAMIC ACID | E | Permitted for use only in combination with other permitted ingredients as a |

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| | | | flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4979 | TRANS-2-OCTENAL | E | trans-2-Octenal must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.<br>The total concentration of the fragrance proprietary excipient formulation containing trans-2-octenal must not be more than 1% of the total medicine. |
| 4980 | TRANS-2-UNDECENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4981 | TRANS-3-HEXENOIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4982 | TRANS-4-DECENAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4983 | TRANS-8-(1-METHYLETHYL)-1-OXASPIRO(4.5)DECAN-2-ONE | E | Permitted for use only in combination with other permitted ingredients as a |

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| | | | fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 4984 | TRANS-ETHYL 2-OCTENOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4985 | TRANS-METHYL-2-HEXENOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 4986 | TREACLE | E | When for oral or sublingual use, sucrose is a mandatory component of treacle. |
| 4987 | TREEMOSS ABSOLUTE | E | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.<br>When included in a medicine for use on the lips the concentration of treemoss absolute must be no more than 0.02%.<br>When for dermal use or use on the hair the concentration of treemoss absolute must be no more than 0.1%<br>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |

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| 4988 | TREFRIW WELLS MINERAL WATER | A | When for internal use, iron is a mandatory component of Trefriw Wells mineral water.<br>Solid dosage forms containing more than 5 milligrams of elemental iron in each dosage unit are required to have a child resistant closure.<br>Liquid Preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.<br>Only able to be used when presented in single use sachets for therapeutic use as an iron supplement. |
| 4989 | 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. |
| 4990 | TREMELLA FUCIFORMIS | A, H | |
| 4991 | TRIACETIN | E | |
| 4992 | TRIACONTANYL PVP | E | Only for use in topical medicines for dermal application. |
| 4993 | TRIADICA SEBIFERA | A, H | |
| 4994 | 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.<br>When used in a solid medicine containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5.<br>When used in a liquid or a semi-solid medicine containing |

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| | | | this ingredient, the pH of the medicine must be no more than 11.5. |
| 4995 | 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.<br>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. |
| 4996 | TRIBEHENIN | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 6%. |
| 4997 | 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.<br>The concentration in the medicine must be no more than 6%. |
| 4998 | TRIBULUS TERRESTRIS | A, E, H | |
| 4999 | TRIBUTYL ACETYLCITRATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5000 | TRICALCIUM PHOSPHATE | E | |
| 5001 | TRICAPRYLIN | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. |

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| | | | The concentration in the medicine must be no more than 5%. |
| 5002 | TRICAPRYLYL CITRATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 7%. |
| 5003 | TRICETEARETH-4 PHOSPHATE | E | Only for use in topical medicines for dermal application. |
| 5004 | TRICHLOROMETHYLPHENYLCARBINYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5005 | TRICHODERMA VIRIDE | A, E, H | |
| 5006 | TRICHOSANTHES KIRILOWII | A, E, H | |
| 5007 | TRICLOSAN | E | The concentration in the medicine must be no more than 1%. |
| 5008 | TRICYCLODECENYL PROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5009 | TRIDECANAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total |

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| | | | fragrance concentration in a medicine must be no more than 1%. |
| 5010 | TRIDECETH-4 PHOSPHATE | E | Only for use in topical medicines for dermal application. |
| 5011 | 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.<br>The concentration in the medicine must be no more than 0.5%. |
| 5012 | TRIDECYL ALCOHOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5013 | TRIDECYL BEHENATE | E | Behenic acid is a mandatory component of Tridecyl behenate.<br>Only for use in topical medicines for dermal application. |
| 5014 | 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.<br>The concentration in the medicine must be no more than 23%. |
| 5015 | TRIDECYL SALICYLATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended |

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| | | | for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 5016 | TRIDECYL STEARATE | E | Only for use in topical medicines for dermal application. |
| 5017 | TRIDECYL TRIMELLITATE | E | Only for use in topical medicines for dermal application. |
| 5018 | TRIETHOXYCAPRYLYLSILANE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.<br>The concentration in the medicine must be no more than 1%. |
| 5019 | TRIETHYL CITRATE | E | |
| 5020 | TRIETHYLENE GLYCOL | E | |
| 5021 | TRIFOLIUM PRATENSE | A, E, H | |
| 5022 | TRIFOLIUM REPENS | A, H | |
| 5023 | TRIGONELLA FOENUM-GRAECUM | A, E, H | |
| 5024 | 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.<br>The concentration in the medicine must be no more than 0.02%. |
| 5025 | TRIHYDROXYSTEARIN | E | Only for use in topical medicines for dermal application. |
| 5026 | TRIISOCETYL CITRATE | E | Only for use in topical medicines for dermal application. |

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| 5027 | TRIISODECYL TRIMELLITATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 5028 | TRIISONONANOIN | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 5029 | TRIISOSTEARIN | E | Only for use in topical medicines for dermal application. |
| 5030 | TRILAURIN | E | Only for use in topical medicines for dermal application. |
| 5031 | TRILISA ODORATISSIMA | A, H | |
| 5032 | TRILLIUM ERECTUM | A, H | |
| 5033 | 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.<br>The concentration in the medicine must be no more than 0.25%. |
| 5034 | TRIMETHYL HYDROXYPENTYL ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 5035 | TRIMETHYL UNDECYLENIC ALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5036 | TRIMETHYL-BICYCLO-HEPTANE-SPIROCYCLOHEXENONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5037 | TRIMETHYLBENZENEPROPANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5038 | TRIMETHYLHEXANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5039 | TRIMETHYLOPROPANE TRIOCTANOATE | E | Only for use in topical medicines for dermal application. |
| 5040 | 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.<br>The concentration in the medicine must be no more than |

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| | | | 5%. |
| 5041 | TRIMETHYLSILOXYSILICATE | E | Only for use in topical medicines for dermal application. |
| 5042 | TRINITROPHENOL | H | Only for use as an active homoeopathic ingredient. |
| 5043 | TRIOCTANOIN | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 5044 | 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.<br>The concentration in the medicine must be no more than 12%. |
| 5045 | TRIOLEIN | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%. |
| 5046 | TRIOSTEUM PERFOLIATUM | A, H | |
| 5047 | TRIOXAUNDECANEDIOIC ACID | E | |
| 5048 | TRIPAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 5049 | 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.<br>The concentration in the medicine must be no more than 0.002%. |
| 5050 | 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.<br>The concentration in the medicine must not be more than 10%.<br>When used topically, the dosage form must not be spray.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 5051 | TRISILOXANE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 40%. |
| 5052 | TRISODIUM EDETATE | E | Only for use in topical medicines for dermal application. |
| 5053 | TRISODIUM | E | Only for use in topical |

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| | ETHYLENEDIAMINE DISUCCINATE | | medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.2%. |
| 5054 | 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.<br>The concentration in the medicine must be no more than 0.005%. |
| 5055 | TRISTEARIN | E | |
| 5056 | 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. |
| 5057 | 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. |
| 5058 | TRIUNDECANOIN | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 11.2%. |
| 5059 | TROLAMINE | E | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 5%. |
| 5060 | TROLAMINE LAURIL SULFATE | E | Only for use in topical |

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| | | | medicines for dermal application. |
| 5061 | 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.<br>The concentration in the medicine must not be more than 12%.<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 5062 | TROLLIUS CHINENSIS | A, H | |
| 5063 | TROMETAMOL | E | |
| 5064 | TROMETAMOL HYDROCHLORIDE | E | |
| 5065 | TROPAEOLUM MAJUS | A, E, H | |
| 5066 | TROPICAL RATTLESNAKE | H | Only for use as an active homoeopathic ingredient. |
| 5067 | TROPOLONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.01%. |
| 5068 | TSUGA CANADENSIS | A, H | |
| 5069 | TULIPA EDULIS | A, H | Colchicine is a mandatory component of Tulipa edulis.<br>The concentration of colchicine in the medicine must be no more than 10 mg/kg or 10 |

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| | | | mg/L or 0.001%. |
| 5070 | TURMERIC | E | Permitted for use only in combination with other permitted ingredients as a colour. |
| 5071 | TURNERA DIFFUSA | A, E, H | Beta-arbutin is a mandatory component of Turnera diffusa.<br>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.<br>When for dermal application exclusively to the face:<br>a) the concentration of beta-arbutin in the medicine must not be more than 7%;<br>b) hydroquinone is a mandatory component; and<br>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.<br>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |
| 5072 | TURNIP | E | |
| 5073 | TURPENTINE OIL | A, E | The concentration in the medicine must be no more than 25%. |
| 5074 | TYPHA ANGUSTIFOLIA | A, H | |
| 5075 | TYPHA LATIFOLIA | A, H | |
| 5076 | TYPHONIUM GIGANTEUM | A, H | |
| 5077 | TYROSINE | A, E | |