

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 | | | |
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| Column 1 | Column 2 | Column 3 | Column 4 |
| Item | Ingredient Name | Purpose | Specific requirements |
| 749 | BACILLUS COAGULANS | A | <p>Only permitted for use in medicines:</p> <p>(a) limited to oral routes of administration; and</p> <p>(b) when the strain of Bacillus coagulans is confirmed to be:</p> <p>(i) Microbial Type Culture Collection (MTCC) accession number 5260; and/or</p> <p>(ii) MTCC accession number 5856.</p> <p>The strain of Bacillus coagulans must be declared on the label.</p> <p>When the strain of Bacillus coagulans is MTCC accession number 5260:</p> <p>(a) the maximum recommended daily dose of the medicine must not provide more than 6 billion cfu of Bacillus coagulans strain MTCC accession number 5260; and</p> <p>(b) the following warning statements are required on the medicine label:</p> <p>- (CHILD2) 'Not suitable for children'; and</p> <p>- (BACCOAG) 'Bacillus coagulans may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect).'</p> |

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When the strain of *Bacillus coagulans* is MTCC accession number 5856:

(a) the maximum recommended daily dose of the medicine must not provide more than 2 billion cfu of *Bacillus coagulans* strain MTCC accession number 5856; and

(b) the following warning statements are required on the medicine label:

- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect);

- (CHILD2) 'Not suitable for children'; and

- (BACCOAG) 'Bacillus coagulans may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect).'

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| 750 | BACKHOUSIA CITRIODORA | A, E, H | <p>The herbal substance must be derived from leaf oil only.</p> <p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 10g/kg or 10g/L or 1%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <p>- (IRRIT) 'If irritation develops - discontinue use'</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended'</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).</p> |
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| 751 | BACOPA MONNIERI | A, H |
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| 752 | BALLOTA NIGRA | A, H | |
| 753 | BALM OF GILEAD BUD DRY | A, H | |
| 754 | BALM OF GILEAD BUD POWDER | A, H | |
| 755 | BALSAM COPAIBA | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 756 | BAMBUSA BREVIFLORA | A, E, H | |
| 757 | BAMBUSA TEXTILIS | A, H | |
| 758 | BANANA | E | |
| 759 | BANANA DISTILLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 760 | BAPTISIA CONFUSA | A, H | |
| 761 | BAPTISIA TINCTORIA | A, H | |
| 762 | BARBAREA VULGARIS | A, H | |
| 763 | BARIUM CARBONATE | H | Only for use as an active homoeopathic ingredient. |
| 764 | BARIUM CHLORIDE | H | Only for use as an active homoeopathic ingredient. |
| 765 | BARIUM SULFATE | E | Only for use in topical medicines for dermal application. |
| 766 | BARLEY | E | Gluten is a mandatory component of Barley when the route of administration is other than topical and mucosal. |
| 767 | BARLEY LEAF | E | |

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| 768 | BASIC BUTYLATED METHACRYLATE COPOLYMER | E | Only for use in oral medicines. |
| 769 | BASIC FUCHSIN | E | Only for use as a colour ingredient in topical medicines for dermal application. |
| 770 | BASIC RED 1 | E | Only for use as a colour in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%. |
| 771 | BASIC VIOLET 11:1 | E | Only for use as a colour in topical medicines for dermal application and not intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%. |
| 772 | BASIL OIL COMOROS | A, E, H | Methyl chavicol is a mandatory component of Basil oil Comoros. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must 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). |
| 773 | BASIL OIL EUROPEAN | A, E, H | Methyl chavicol is a mandatory component of Basil oil European. When the concentration of Methyl chavicol in the medicine is more |

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| | | | <p>than 5%, the nominal capacity of the container must be no more than 25mL.</p> <p>When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p> |
| 774 | BASSIA SCOPARIA | A, H | |
| 775 | BATYL ALCOHOL | E | Only for use in topical medicines for dermal application. |
| 776 | BAY LEAF | E | |
| 777 | BAY OIL | A, E, H | <p>When the total concentration of bay oil in the medicine is more than 25%:</p> <p>(a) the nominal capacity of the container must not be more than 25 mL;</p> <p>(b) the container must be fitted with a restricted flow insert;</p> <p>(c) the following warning statements are required on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or word to that effect);</p> <p>- (NTAKEN) 'Not to be taken';</p> <p>and</p> <p>(d) when the nominal capacity of the container is greater than 15 mL, the container must also be fitted with a child resistant closure.</p> |
| 778 | BEEWAX ABSOLUTE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a |

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| | | | <p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 779 | BEESWAX ALCOHOLS | A | <p>Only to be used in a medicine where Rainbow and Nature Pty Ltd (Client ID 22307), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 22 April 2024.</p> <p>The route of administration for medicines that contain beeswax alcohols must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 150 mg beeswax alcohols.</p> <p>The following warning statements (or words to the same effect) are required on the medicine label:</p> <p>(a) (PREGNT) ‘Not recommended for use by pregnant and lactating women’</p> <p>(b) (CHILD2) ‘Not suitable for children’</p> |
| 780 | BEET RED | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 781 | BEETROOT | E, H | |
| 782 | BEGONIA FIMBRISTIPULA | A, H | |
| 783 | BEHENETH-10 | E | Only for use in topical medicines |

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| | | | for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%. Residual levels of ethylene oxide are to be kept below the level of detection. |
| 784 | BEHENIC ACID | E | When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid. |
| 785 | BEHENOXY DIMETHICONE | E | Only for use in topical medicines for dermal application. |
| 786 | BEHENOYL STEARIC ACID | E | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.4%. |
| 787 | BEHENYL ALCOHOL | E | Only for use in topical medicines for dermal application. |
| 788 | BELLADONNA HERB DRY | A, H | Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb dry. The concentration of alkaloids calculated as hyoscyamine in the medicine and must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%. |
| 789 | BELLADONNA HERB POWDER | A, H | Alkaloids calculated as hyoscyamine and atropine are |

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| | | | <p>mandatory components of Belladonna herb powder.</p> <p>The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.</p> <p>The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.</p> |
| 790 | BELLADONNA HERB PREPARED | A, H | <p>Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb prepared and must be declared in the application.</p> <p>The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.</p> <p>The concentration of atropine from all ingredients in the product must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.</p> |
| 791 | BELLIS PERENNIS | A, H | |
| 792 | BEMOTRIZINOL | A | <p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> |

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| | | | - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 793 | BENINCASA HISPIDA | A, E, H | |
| 794 | BENTONITE | E | |
| 795 | BENZALDEHYDE | E | |
| 796 | BENZALDEHYDE GLYCERYL ACETAL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 797 | BENZALKONIUM CHLORIDE | E | Only for use in topical medicines for dermal application and nasal sprays. When benzalkonium chloride is used in a topical medicine for dermal application, the concentration in the medicine must not be more than 5%. When benzalkonium chloride is used in a nasal spray dosage form, the concentration of benzalkonium chloride in the medicine must not be more than 0.03%. When benzalkonium chloride is used in a nasal spray dosage form which is either: (i) indicated for use in children; or (ii) not specifically indicated for adults only; the following warning statement is required on the medicine label: - (NTAKEN2) 'Not to be used by children under 2 years old' (or words to that effect). |
| 798 | BENZETHONIUM CHLORIDE | E | Only for use as a preservative in topical medicines for dermal |

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| | | | application. |
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| 799 | BENZOIC ACID | E, H | |
| 800 | BENZOIN | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 801 | BENZOIN SIAM | A, E, H | |
| 802 | BENZOIN SUMATRA | A, E, H | |
| 803 | BENZOPHENONE | E | Permitted for topical use only in combination with other permitted ingredients as a fragrance. The total concentration of fragrance proprietary excipient formulations containing benzophenone must not be more than 1% of the total medicine. |
| 804 | BENZOTHIAZOLE | E | Benzothiazole must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing benzothiazole must not be more than 1% of the total medicine. |
| 805 | BENZYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a |

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| | | | medicine must be no more 1%. |
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| 806 | BENZYL ACETONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 807 | BENZYL ALCOHOL | A, E | When used as an active ingredient: a) permitted for use only in medicated throat lozenges; and b) when the maximum recommended daily dose of the medicine provides more than 300mg, the following warning statement must be included on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect). |
| 808 | BENZYL BENZOATE | E | Only for use in topical medicines for dermal application. |
| 809 | BENZYL BUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 810 | BENZYL CINNAMATE | E | Only for use in: (a) topical medicines for dermal application when the concentration of benzyl cinnamate in the medicine is not greater than |

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| | | | 0.15%; or (b) medicines in combination with other permitted ingredients as a constituent of a flavour proprietary excipient formulation when the total flavour proprietary excipient formulation in the medicine is not more than 5%. Not to be included in medicines intended for use in the eye. |
| 811 | BENZYL DIMETHYL CARBINYL-N-BUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 812 | BENZYL FORMATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 813 | BENZYL ISOAMYL ETHER | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 814 | BENZYL ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total |

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| | | | flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 815 | BENZYL ISOVALERATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 816 | BENZYL LAURATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 817 | BENZYL PHENYLACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 818 | BENZYL PROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total |

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| | | | flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 819 | BENZYL SALICYLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 820 | BENZYL TIGLATE | E | Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. |
| 821 | BENZYLIDENE ACETONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 822 | BENZYLIDENE CAMPHOR SULFONIC ACID | A | Only for use as an active ingredient in sunscreens for dermal application and not to be |

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| | | | <p>included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 6% (as acid).</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 823 | BERBERIS AQUIFOLIUM | A, H | |
| 824 | BERBERIS ARISTATA | A | <p>Only for use in oral medicines.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect). |
| 825 | BERBERIS VULGARIS | A, E, H | |
| 826 | BERGAMOT OIL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour, the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (SENS) 'Application to skin may increase sensitivity to sunlight.' |

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| 827 | BERGAMOT OIL BERGAPTEN-FREE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 828 | BERGAMOT OIL COLDPRESSED | A, E, H | <p>When for internal use oxedrine is a mandatory component of bergamot oil coldpressed.</p> <p>The maximum recommended daily dose must provide no more than 30 milligrams of oxedrine.</p> <p>The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.4 per cent or less of bergamot oil coldpressed; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p> |
| 829 | BERGAMOT OIL TERPENELESS | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 830 | BERTHOLLETIA EXCELSA | A, E, H | |

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| 831 | BETA RAPA | A, E, H | |
| 832 | BETA VULGARIS | A, E, H | |
| 833 | BETA,4-DIMETHYLCYCLOHEX-3-ENE-1-PROPAN-1-AL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 834 | BETA-CARYOPHYLLENE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 835 | BETA-CARYOPHYLLENE ALCOHOL | E | Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. |
| 836 | BETA-DAMASCENONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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| 837 | BETA-DAMASCONONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 838 | BETA-HOMO CYCLOCITRAL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 839 | BETA-HYDROXY-BETA-METHYLBUTYRIC ACID | A | |
| 840 | BETA-IONONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 841 | BETA-IONONE EPOXIDE | E | Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. |
| 842 | BETA-ISO-METHYL IONONE | E | Permitted for use only in |

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| | | | <p>combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 843 | BETA-METHYL NAPHTHYL KETONE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 844 | BETA-N-METHYL IONONE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 845 | BETA-NAPHTHOL ETHYLEETHER | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 846 | BETA-NAPHTHOL METHYL | E | Permitted for use only in |

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| | ETHER | | <p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 847 | BETA-NAPHTHYL ANTHRANILATE | E | <p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> |
| 848 | BETA-NAPHTHYL ISOBUTYL ETHER | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 849 | BETA-PINENE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |

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| 850 | BETA-TOCOPHEROL | E | |
| 851 | BETACAROTENE | A, E | When Vitamin A is declared as an equivalent of Betacarotene and the medicine is for oral or sublingual use in adults the medicine requires the following warning statement on the medicine label: - (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.' |
| 852 | BETADEX | E | |
| 853 | BETAGLUCAN | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%. |
| 854 | BETAINE | E | Only for use in topical medicines for dermal application. |
| 855 | BETAINE HYDROCHLORIDE | E | |
| 856 | BETULA LENTA | A, H | Methyl salicylate is a mandatory component of Betula lenta. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl |

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salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:

- the delivery device is engaged into the container in such a way that prevents it from being readily removed;

- direct suction through the delivery device results in delivery of no more than one dosage unit; and

- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).

When for use in topical medicines for dermal application:

i) the concentration of methyl salicylate in the medicine must not be more than 25%;

ii) the following warning statements are required on the medicine label:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);

- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';

- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);

iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following

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| | | | <p>warning statement is required on the medicine label:</p> <p>- (IRRIT) 'If irritation develops, discontinue use'.</p> |
| 857 | BETULA NIGRA | A, H | <p>Cresol, eugenol and methyl salicylate are mandatory components of <i>Betula nigra</i>.</p> <p>For external use only when the total concentration of cresols, xylenols and other phenol homologues in the medicine is greater than 3%.</p> <p>When for internal use, the concentration of eugenol in the medicine must not exceed 0.06%.</p> <p>When the concentration of eugenol in the medicine is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 mL;</p> <p>b) the medicine must be fitted with a restricted flow insert;</p> <p>c) when the nominal capacity of the container is more than 15 mL, the medicine must be fitted with a child resistant closure; and</p> <p>d) the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is</p> |

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more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.

When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:

- the delivery device is engaged into the container in such a way that prevents it from being readily removed;
- direct suction through the delivery device results in delivery of no more than one dosage unit; and
- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).

When for use in topical medicines for dermal application:

- i) the concentration of methyl salicylate in the medicine must not be more than 25%;
 - ii) the following warning statements are required on the medicine label:
 - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);
 - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';
 - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);
 - (AVOID) 'Avoid prolonged
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| | | | <p>exposure in the sun' (or words to that effect);</p> <p>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <p>- (IRRIT) 'If irritation develops, discontinue use'.</p> |
| 858 | BETULA PENDULA | A, E, H | <p>Methyl salicylate is a mandatory component of Betula pendula.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. <p>The following warning statement is required on the medicine label:</p> |

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| | | | <p>- (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25% ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.</p> |
| 859 | BETULA PUBESCENS | A, E, H | |
| 860 | BICYCLO(2.2.1)HEPT-5-ENE-2-CARBOXYLIC ACID, 3-(1-METHYLETHYL)-, ETHYL ESTER, (1R,2R,3R,4S)-REL- | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 861 | BICYCLO(2.2.2)OCT-5-ENE-2-CARBOXALDEHYDE, 6-METHYL-8-(1-METHYLETHYL)- | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total</p> |

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| | | | fragrance concentration in a medicine must be no more than 1%. |
| 862 | BIFIDOBACTERIUM ADOLESCENTIS | A | |
| 863 | BIFIDOBACTERIUM ANIMALIS | A | |
| 864 | BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS | A | |
| 865 | BIFIDOBACTERIUM ANIMALIS SSP LACTIS | A | |
| 866 | BIFIDOBACTERIUM BIFIDUM | A | |
| 867 | BIFIDOBACTERIUM BREVE | A | |
| 868 | BIFIDOBACTERIUM INFANTIS | A | |
| 869 | BIFIDOBACTERIUM LACTIS | A | |
| 870 | BIFIDOBACTERIUM LONGUM | A | |
| 871 | BILBERRY | E | |
| 872 | BIOSACCHARIDE GUM-1 | E | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. |
| 873 | BIOTA ORIENTALIS | A, H | |
| 874 | BIOTIN | A, E | |
| 875 | BIRCH LEAF DRY | A, E, H | Methyl salicylate is a mandatory component of birch leaf dry. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl |

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salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:

- the delivery device is engaged into the container in such a way that prevents it from being readily removed;

- direct suction through the delivery device results in delivery of no more than one dosage unit; and

- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).

When for use in topical medicines for dermal application:

i) the concentration of methyl salicylate in the medicine must not be more than 25%

ii) the following warning statements are required on the medicine label:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);

- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';

- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);

iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on

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| | | | the medicine label: - (IRRIT) 'If irritation develops, discontinue use'. |
| 876 | BIRCH TAR OIL RECTIFIED | A, E, H | Cresol is a mandatory component of birch tar oil rectified. For external use only when the total concentration of cresols, xylenols and other phenol homologues in the medicine is greater than 3%. |
| 877 | BIS-BUTYLDIMETICONE POLYGLYCERYL-3 | E | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1.5%. |
| 878 | BIS-DIGLYCERYL POLYACYLADIPATE-2 | E | Only for use in topical medicines for dermal application. |
| 879 | BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYL MALONATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. |
| 880 | BIS-MACROGOL 900 METHYL ETHER DIMETHYL SILANE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2.5%. |
| 881 | BIS-PEG-12 DIMETHICONE BEESWAX | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine |

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| | | | must be no more than 0.2%. |
| 882 | BIS-STEARYL DIMETICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 2.30%. |
| 883 | BIS-STEARYL ETHYLENEDIAMINE/NEOPENTYL GLYCOL/STEARYL HYDROGENATED DIMER DILINOLEATE COPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%. |
| 884 | BISABOLENE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 885 | BISABOLOL | E | If used as an excipient, the medicine is only for use in topical medicines for dermal application. |
| 886 | BITTER ALMOND OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. The absence of amygdalin in the medicine must be declared. |
| 887 | BITTERN | A, E, H | Magnesium is a mandatory |

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| | | | <p>component of bittern.</p> <p>Only permitted for use in:</p> <p>(a) medicines limited to oral routes of administration; and</p> <p>(b) topical medicines for dermal administration.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p> |
| 888 | BIXA ORELLANA | A, E, H | |
| 889 | BLACK BONED CHICKEN POWDER | A | |
| 890 | BLACK COHOSH DRY | A, H | <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (BCOHOSH) 'Warning: In very</p> |

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| | | | <p>rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'</p> |
| 891 | BLACK COHOSH POWDER | A, H | <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'</p> |
| 892 | BLACK CURRANT | E | |
| 893 | BLACK CURRANT ABSOLUTE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 894 | BLACK CURRANT FRESH | A, E, H | |
| 895 | BLACK CURRANT SEED OIL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total</p> |

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| | | | flavour concentration in a medicine must be no more than 5%. |
| 896 | BLACK OF CURACAO SPIDER | H | Only for use as an active homoeopathic ingredient. |
| 897 | BLACK PEPPER OIL | A, E, H | |
| 898 | BLACK RASPBERRY | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 899 | BLACK SNAKE | H | Only for use as an active homoeopathic ingredient. |
| 900 | BLACKBERRY | E | |
| 901 | BLACKBERRY OILS | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 902 | BLACKBERRY WINE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 903 | BLACKCURRANT ESTERS | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

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| 904 | BLACKCURRANT JUICE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 905 | BLACKSTRAP MOLASSES | E | When for oral or sublingual use, sucrose is a mandatory component of blackstrap molasses. |
| 906 | BLADDERWRACK DRY | A, H | Iodine is a mandatory component of Bladderwrack dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 907 | BLADDERWRACK POWDER | A, H | Iodine is a mandatory component of Bladderwrack powder. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 908 | BLAINVILLEA ACMELLA | A, E, H | When used as an excipient, permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total |

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| | | | flavour concentration in a medicine must be no more than 5%. |
| 909 | BLETILLA STRIATA | A, H | |
| 910 | BLUE FLAG RHIZOME DRY | A, H | |
| 911 | BLUE FLAG RHIZOME POWDER | A, H | |
| 912 | BLUEBERRY | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 913 | BLUEBERRY JUICE | E | Permitted for use only in combination with other permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 914 | BLUMEA LACERA | A, H | |
| 915 | BOEHMERIA NIVEA | A, H | |
| 916 | BOERHAVIA DIFFUSA | A, H | |
| 917 | BOERHAVIA REPENS | A, H | |
| 918 | BOGBEAN LEAF DRY | A, H | |
| 919 | BOGBEAN LEAF POWDER | A, H | |
| 920 | BOIS DE ROSE OIL | A, E, H | |
| 921 | BOMBAX CEIBA | A, H | |
| 922 | BORAGO OFFICINALIS | A, E, H | Only for use when the preparation is 'fixed oil' and the fixed oil is derived from seeds of <i>Borago officinalis</i> . |
| 923 | BORAX | A, E, H | Boron is a mandatory component |

of borax.

The percentage of boron from borax should be calculated based on the molecular weight of borax.

The maximum recommended daily dose must not provide more than 6mg of boron.

In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%.

When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:

- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or

- (ADULT) 'Adults only' (or words to that effect).

When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:

- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or

- (ADULT) 'Adults only' (or words to that effect).

When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or

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| | | | <p>oral application, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> - (BORON) 'Contains boron' (or words to that effect). <p>When the medicine is for topical use for dermal application, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> - (BROKEN) 'Use on unbroken skin only' (or words to that effect). |
| 924 | BORAX PENTAHYDRATE | A, E | <p>Boron is a mandatory component of borax pentahydrate.</p> <p>The percentage of boron from borax pentahydrate should be calculated based on the molecular weight of borax pentahydrate.</p> <p>The maximum recommended daily dose must not provide more than 6mg of boron from borax pentahydrate.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must not be more than 3500 mg/kg or 3500 g/L or 0.35%.</p> <p>When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> - (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). <p>When the maximum recommended daily dose of the medicine provides more than 1 mg</p> |

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| | | | <p>boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> - (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). <p>When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> - (BORON) 'Contains boron' (or words to that effect). <p>When the medicine is for topical use for dermal application, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> - (BROKEN) 'Use on unbroken skin only' (or words to that effect). |
| 925 | BORIC ACID | A, H | <p>Boron is a mandatory component of boric acid.</p> <p>The percentage of boron from boric acid should be calculated based on the molecular weight of boric acid.</p> <p>The maximum recommended daily dose must not provide more than 6mg of boron.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must not be more than 3500 mg/kg or 3500 mg/L or 0.35%.</p> <p>When the maximum recommended daily dose of the</p> |

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| | | | <p>medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> - (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). <p>When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> - (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). <p>When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> - (BORON) 'Contains boron' (or words to that effect). <p>When the medicine is for topical use for dermal application, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> - (BROKEN) 'Use on unbroken skin only' (or words to that effect). |
| 926 | BORNEOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a |

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| | | | <p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 927 | BORNYL ACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 928 | BORON NITRIDE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.5%.</p> |
| 929 | BORONIA ABSOLUTE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 930 | BORONIA MEGASTIGMA | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |

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| 931 | BOSWELLIA CARTERII | A, E, H | |
| 932 | BOSWELLIA SERRATA | A, E, H | |
| 933 | BOSWELLIA THURIFERA | A, H | |
| 934 | BOVINE CALCIUM CHONDROITIN SULFATE | A | |
| 935 | BOVINE CHONDROITIN SULFATE | A | |
| 936 | BOVINE COLOSTRUM POWDER | A | The following warning statement is required on the medicine label: - (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect). |
| 937 | BOVINE LACTOFERRIN | A | |
| 938 | BOVINE POTASSIUM CHONDROITIN SULFATE | A | |
| 939 | BOVINE SODIUM CHONDROITIN SULFATE | A, E | When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%. |
| 940 | BOVINE WHEY IG-RICH FRACTION | A | Only for use in oral medicines. The following warning statement is required on the medicine label: - (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect). |
| 941 | BRANDY | E | |
| 942 | BRASSICA CAMPESTRIS/ALEURITES FORDI OIL COPOLYMER | E | Only for use in topical medicines for dermal application and not for use in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. |

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| 943 | BRASSICA CHINENSIS | A, H | <p>Allyl isothiocyanate is a mandatory component of Brassica chinensis when the plant part is seed.</p> <p>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%.</p> |
| 944 | BRASSICA JUNCEA | A, H | <p>Allyl isothiocyanate is a mandatory component of Brassica juncea when the plant part is seed.</p> <p>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%.</p> |
| 945 | BRASSICA NAPUS | A, E, H | <p>Allyl isothiocyanate is a mandatory component of Brassica napus when the plant part is seed.</p> <p>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%.</p> |
| 946 | BRASSICA NIGRA | A, H | <p>Allyl isothiocyanate is a mandatory component of Brassica nigra when the plant part is seed.</p> <p>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%.</p> |
| 947 | BRASSICA OLERACEA VAR. BOTRYTIS | A, E, H | <p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. botrytis when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients</p> |

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| | | | in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%. |
| 948 | BRASSICA OLERACEA VAR. CAPITATA | A, E, H | <p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. capitata when the plant part is seed.</p> <p>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%.</p> |
| 949 | BRASSICA OLERACEA VAR. GEMMIFERA | A, H | <p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var gemmifera when the plant part is seed.</p> <p>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%.</p> |
| 950 | BRASSICA OLERACEA VAR. ITALICA | A, H | <p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. italica when the plant part is seed.</p> <p>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%.</p> |
| 951 | BRASSICA OLERACEA VAR. VIRIDIS | A, H | <p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. viridis when the plant part is seed.</p> <p>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%.</p> |

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| 952 | BRASSICA PEKINENSIS | A, H | Allyl isothiocyanate is a mandatory component of Brassica pekinensis when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%. |
| 953 | BRASSICA RAPA | A, E, H | Allyl isothiocyanate is a mandatory component of Brassica rapa when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%. |
| 954 | BRILLIANT BLACK BN | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 955 | BRILLIANT BLUE FCF | E | Permitted for use only as a colour for oral, topical and dental use. |
| 956 | BRILLIANT BLUE FCF ALUMINIUM LAKE | E | Permitted for use only as a colour for oral and topical use. |
| 957 | BRILLIANT BLUE FCF BARIUM LAKE | E | Permitted for use only as a colour for oral and topical use. |
| 958 | BRILLIANT SCARLET 4R | E | Permitted for use only as a colour in medicines for topical and oral routes of administration. |
| 959 | BRILLIANT SCARLET 4R ALUMINIUM LAKE | E | Permitted for use only as a colour in medicines for topical and oral routes of administration. |
| 960 | BRIZA MEDIA | A, H | |
| 961 | BROCCOLI | E | |

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| 962 | BROMELAINS | A | May be derived from either the stem or fruit of the pineapple (<i>Ananas comosus</i>). |
| 963 | BROMOSTYROL | E | Not for use in infants Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 964 | BROMUS CATHARTICUS | A, H | |
| 965 | BROMUS INERMIS | A, H | |
| 966 | BROMUS RAMOSUS SUBSP. RAMOSUS | A, H | |
| 967 | BRONOPOL | E | Only for use in topical medicines for dermal application. |
| 968 | BROUSSONETIA POPYRIFERA | A, H | |
| 969 | BROWN FK | E | Permitted for use only as a colour for topical use. |
| 970 | BRUNFELSIA UNIFLORA | A, H | The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 971 | BRUSSEL SPROUT | E | |
| 972 | BRYONIA ALBA | A, H | |
| 973 | BRYONIA DIOICA | A, H | |
| 974 | BUCHU LEAF DRY | A, H | |
| 975 | BUCHU LEAF OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total |

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| | | | fragrance concentration in a medicine must be no more 1%. |
| 976 | BUCHU LEAF POWDER | A, E, H | |
| 977 | BUCKWHEAT | E, H | Only for use as an active homoeopathic or excipient ingredient. |
| 978 | BUDDLEJA OFFICINALIS | A, H | |
| 979 | BULNESIA SARMIENTI | A, E, H | |
| 980 | BUNIAS ORIENTALIS | A, H | |
| 981 | BUPLEURUM FALCATUM | A, H | |
| 982 | BURDOCK LEAF DRY | A, H | |
| 983 | BURDOCK LEAF POWDER | A, H | |
| 984 | BURDOCK ROOT DRY | A, H | |
| 985 | BURDOCK ROOT POWDER | A, H | |
| 986 | BUSHMASTER SNAKE | H | Only for use as an active homoeopathic ingredient. |
| 987 | BUTAN-1-OL | E | The residual solvent limit for Butan-1-ol is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%. |
| 988 | BUTANE | E | Only for use as an excipient propellant ingredient. |
| 989 | BUTOXYETHANOL | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%. |
| 990 | BUTTER | E | |
| 991 | BUTTER ACIDS | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a |

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| | | | medicine must be no more than 5%. |
| 992 | BUTTER ESTERS | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 993 | BUTTER STARTER DISTILLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 994 | BUTYL 2-METHYLBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 995 | BUTYL ACETATE | E | The residual solvent limit for Butyl acetate is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%. |
| 996 | BUTYL BUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total |

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| | | | fragrance concentration in a medicine must be no more 1%. |
| 997 | BUTYL BUTYRYL LACTATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 998 | BUTYL CAPROATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 999 | BUTYL ESTER OF PVM/MA COPOLYMER | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 15%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (EYE) 'Avoid contact with eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect). |
| 1000 | BUTYL FORMATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |

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| 1001 | BUTYL HYDROXYBENZOATE | E | Only for use in topical medicines for dermal application. |
| 1002 | BUTYL ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1003 | BUTYL ISOVALERATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1004 | BUTYL LACTATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1005 | BUTYL LEVULINATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1006 | BUTYL METHOXYDIBENZOYLMETHAN E | A | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in preparation must not be more than 5%. |

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| | | | When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 1007 | BUTYL PROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1008 | BUTYL STEARATE | E | Only for use in topical medicines for dermal application. |
| 1009 | BUTYL UNDECYLENATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1010 | BUTYLATED HYDROXYANISOLE | E | |
| 1011 | BUTYLATED HYDROXYTOLUENE | E | |
| 1012 | BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE | 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 10%. |
| 1013 | BUTYLIDENE PHTHALIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1014 | BUTYLOCTYL SALICYLATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%. |
| 1015 | BUTYLPHENYL METHYLPROPIONAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1016 | BUTYRALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1017 | BUTYRIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total |

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| | | | flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1018 | C1-8 ALKYL TETRAHYDROXYCYCLOHEXAN OATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.012%. |
| 1019 | C10-12 ALKANE/CYCLOALKANE | E | Only permitted for use in solid or semi-solid medicines or in medicines: (a) containing 25% or less of hydrocarbons, liquid; or (b) when packed in pressurised spray packs; or (c) when packed in containers with a capacity of 2 millilitres or less. Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must not be more than 1%. |
| 1020 | C10-30 CHOLESTEROL/LANOSTEROL ESTERS | E | Only for use in topical medicines for dermal application. |
| 1021 | C11-13 ALKANE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. |
| 1022 | C11-14-ISO-ALCOHOL C-13 RICH | E | Permitted for use only in |

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| | | | <p>combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1023 | C12-13 PARETH-23 | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.125%.</p> <p>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.</p> |
| 1024 | C12-13 PARETH-3 | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.125%.</p> <p>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.</p> |
| 1025 | C12-15 ALKYL LACTATE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1.2%.</p> |
| 1026 | C12-15 ALKYL OCTANOATE | E | <p>Only for use in topical medicines for dermal application.</p> |
| 1027 | C12-20 ACID PEG-8 ESTER | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> |

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| | | | The concentration in the medicine must be no more than 0.2%. |
| 1028 | C12-20 ALKYL GLUCOSIDE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.75%.</p> |
| 1029 | C12-22 ALKYL ACRYLATE/HYDROXYETHYLACRYLATE COPOLYMER | E | <p>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.</p> <p>The concentration of C12-22 alkyl acrylate/hydroxyethylacrylate copolymer in the medicine must not be more than 5%.</p> |
| 1030 | C13-14 ISOPARAFFIN | E | Only for use in topical medicines for dermal application. |
| 1031 | C14-22 ALCOHOLS | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2.55%.</p> |
| 1032 | C15-16 ISOPARAFFIN | E | <p>C15-16 isoparaffin must only be included in topical medicines:</p> <p>(a) for dermal application; and</p> <p>(b) where the dosage form of the medicine is not spray.</p> <p>The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%.</p> <p>When the nominal capacity of the container is more than 2 mL and the medicine is not a solid or semi-solid preparation, the total</p> |

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| | | | concentration of designated solvents (including C15-16 isoparaffin) in the medicine must not be more than 25%. |
| 1033 | C15-19 ALKANE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 7%.</p> |
| 1034 | C17-18 ISOPARAFFIN | E | <p>C17-18 isoparaffin must only be included in topical medicines:</p> <p>(a) for dermal application; and</p> <p>(b) where the dosage form of the medicine is not spray.</p> <p>The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%.</p> <p>When the nominal capacity of the container is more than 2 mL and the medicine is not a solid or semi-solid preparation, the total concentration of designated solvents (including C17-18 isoparaffin) in the medicine must not be more than 25%.</p> |
| 1035 | C18-36 ACID GLYCOL ESTER | E | Only for use topical medicines for dermal application. |
| 1036 | C18-36 ACID TRIGLYCERIDE | E | Only for use in topical medicines for dermal application. |
| 1037 | C2-OCTENAL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |

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| 1038 | C20-40 ALCOHOLS | E | Only for use in topical medicines for dermal application. |
| 1039 | C20-40 ALKYL STEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. |
| 1040 | C20-40 PARETH-24 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.25%. |
| 1041 | C20-40 PARETH-3 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. |
| 1042 | C30-45 ALKYL CETEARYL DIMETICONE CROSSPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. |
| 1043 | C9-11 ISOPARAFFIN | E | Only for use in topical medicines for dermal application. |
| 1044 | C9-11 PARETH-3 | E | Only for use in topical medicines for dermal application. |
| 1045 | C9-15 ALKYL PHOSPHATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. |

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| | | | The concentration in the medicine must be no more than 0.12% |
| 1046 | CABBAGE | E | |
| 1047 | CABREUVA OIL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1048 | CADE OIL | A, E, H | |
| 1049 | CAESALPINIA SAPPAN | A, H | |
| 1050 | CAFFEINE | A, E, H | When used as an excipient, only for use in topical medicines for dermal application. Only for use as an active ingredient for: (a) oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine); and (b) Topical medicines for dermal application that are directed for use in adults only. When for topical application: (a) the concentration of total caffeine in the medicine must not be more than 1%; and (b) the medicine must not be intended for use on broken skin. When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 100 mg of caffeine from this ingredient. When for internal use or oral application, the following warning statement is required on the |

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medicine label:

- (ADULT) 'Adults only' (or words to that effect).

When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.

When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine.'

- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following

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| | | | <p>warning statements are required on the label:</p> <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect). |
| 1051 | CAJUPUT OIL | A, E, H | <p>Cineole is a mandatory component of Cajuput oil.</p> <p>When the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is less than 15 mL, a restricted flow insert must be fitted to the container.</p> <p>When the concentration in the medicine is more than 25%, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. <p>When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 mL.</p> |

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| | | | <p>When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, the medicine must have a child resistant closure and restricted flow insert fitted on the container and the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. <p>When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, the medicine must have the restricted flow insert fitted on the container and the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. |
| 1052 | CALAMINE | A, E | <p>Only for use as an active or excipient ingredient for dermal application.</p> <p>When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.</p> |
| 1053 | CALANUS FINMARCHICUS OIL | A | <p>Only to be used in a medicine where Blackmores Ltd (Client ID 10576), who applied to have the ingredient included in this Determination, is the sponsor of</p> |

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| | <p>the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 March 2025.</p> <p>The route of administration for medicines that contain <i>Calanus finmarchicus</i> oil must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 2.3 g of <i>Calanus finmarchicus</i> oil.</p> <p>The following warning statements (or words to that effect) are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'. |
| <p>1054 CALCIFEDIOL MONOHYDRATE A</p> | <p>The maximum recommended daily dose of the medicine must not provide more than 10 micrograms of calcifediol.</p> <p>Only for use in oral medicines.</p> <p>Calcifediol must not be used in medicines with other Vitamin D analogues; such as ergocalciferol or colecalciferol.</p> <p>The medicine requires the following warning statements on the label:</p> <ul style="list-style-type: none"> - (CFEDIOL) 'Calcifediol may have similar effects to Vitamin D. Consult your health care professional before taking in combination with other medicines.' (or words to that effect); - (OTHVITD) 'The medicine should not be taken in combination with supplements |

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| | | | containing Vitamin D without medical advice' (or words to that effect); - (CHILD9) 'Use in children under 9 years is not recommended' (or words to that effect). |
| 1055 | CALCIFIED LITHOTHAMNION SPECIES | A | Only for use in oral medicines. |
| 1056 | CALCIFIED LITHOTHAMNION TOPHIFORME | A | Only for oral use. |
| 1057 | CALCIUM ALGINATE | E | |
| 1058 | CALCIUM AMINO ACID CHELATE | A, H | Calcium is a mandatory component of calcium amino acid chelate. The concentration of calcium in the calcium amino acid chelate must be no more than 25% w/w. |
| 1059 | CALCIUM ASCORBATE | A, E, H | |
| 1060 | CALCIUM ASCORBATE DIHYDRATE | A, E, H | |
| 1061 | CALCIUM ASPARTATE | A | |
| 1062 | CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE | A | Only for use in oral medicines. |
| 1063 | CALCIUM BEHENATE | E | Behenic acid is a mandatory component of Calcium behenate. When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 mg of Behenic acid. |
| 1064 | CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE | A, H | |
| 1065 | CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE | A, H | |
| 1066 | CALCIUM CARBONATE | A, E, H | |
| 1067 | CALCIUM CASEINATE | E | |
| 1068 | CALCIUM CHLORIDE DIHYDRATE | E | |

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| 1069 | CALCIUM CITRATE | A, E, H | |
| 1070 | CALCIUM CITRATE TETRAHYDRATE | A, E, H | |
| 1071 | CALCIUM DIASPARTATE | A | Only for use in oral medicines. |
| 1072 | CALCIUM FLUORIDE | H | The percentage of fluoride from Calcium fluoride should be calculated based on the molecular weight of Calcium fluoride. The concentration of fluoride in the product from all ingredients must be no more than 10mg/kg or 10mg/L or 0.1%. |
| 1073 | CALCIUM FOLINATE | A | Folinic acid is a mandatory component of calcium folinate. The maximum recommended daily dose must not provide more than 500 micrograms of folinic acid. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. |
| 1074 | CALCIUM FRUCTOBORATE TETRAHYDRATE | A | Only to be used in a medicine where VDF FutureCeuticals Inc (Client ID 62256), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 25 October 2025. Boron is a mandatory component of calcium fructoborate |

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| | | | <p>tetrahydrate.</p> <p>The percentage of boron from calcium fructoborate tetrahydrate should be calculated based on the molecular weight of calcium fructoborate tetrahydrate.</p> <p>The route of administration for medicines that contain calcium fructoborate tetrahydrate must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(a) 220 mg of calcium fructoborate tetrahydrate; and</p> <p>(b) 6 mg of boron.</p> <p>The following warning statements (or words to the same effect) are required on the medicine label:</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women'; and</p> <p>- (ADULT) 'Adults only'.</p> |
| 1075 | CALCIUM GLUCONATE MONOHYDRATE | A, E, H | |
| 1076 | CALCIUM GLYCEROPHOSPHATE | A, E, H | |
| 1077 | CALCIUM GLYCINATE | A | Only for use in oral medicines. |
| 1078 | CALCIUM GLYCINATE DIHYDRATE | A | |
| 1079 | CALCIUM HEXAFLUOROSILICATE | H | Only for use as an active homoeopathic ingredient. |
| 1080 | CALCIUM HYDROGEN PHOSPHATE | A, E, H | |
| 1081 | CALCIUM HYDROGEN PHOSPHATE DIHYDRATE | A, E, H | |
| 1082 | CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE | A, E, H | |
| 1083 | CALCIUM HYDROXIDE | A, E, H | When used as a standard active |

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| | | | 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. |
| 1084 | CALCIUM HYDROXYCITRATE | A, H | |
| 1085 | CALCIUM HYPOPHOSPHITE | H | Only for use as an active homoeopathic ingredient. |
| 1086 | CALCIUM IODIDE | H | Only for use as an active homoeopathic ingredient. |
| 1087 | CALCIUM KETOGLUCONATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration must be no more than 1% |
| 1088 | CALCIUM L-THREONATE | A | Only for use in oral medicines. |
| 1089 | CALCIUM LACTATE | A, E, H | |
| 1090 | CALCIUM LACTATE GLUCONATE | A, E, H | |
| 1091 | CALCIUM LACTATE PENTAHYDRATE | A, E, H | |
| 1092 | CALCIUM LACTATE TRIHYDRATE | A, E, H | |
| 1093 | CALCIUM LYSINATE | A | Only for use in oral medicines. |
| 1094 | CALCIUM METHIONINATE | A | Only for use in oral medicines. |
| 1095 | CALCIUM OROTATE | A, E, H | |
| 1096 | CALCIUM OXIDE | E | Only for use in topical medicines for dermal application. |

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| 1097 | CALCIUM PANTOTHENATE | A, E, H | |
| 1098 | CALCIUM PHOSPHATE | A, E, H | |
| 1099 | CALCIUM PYRUVATE | A | |
| 1100 | CALCIUM SACCHARATE | E | |
| 1101 | CALCIUM SILICATE | E | |
| 1102 | CALCIUM SODIUM CASEINATE | A, H | |
| 1103 | CALCIUM SODIUM LACTATE | A, E, H | |
| 1104 | CALCIUM STEARATE | E | |
| 1105 | CALCIUM SUCCINATE | A, E, H | |
| 1106 | CALCIUM SULFATE | A, E, H | |
| 1107 | CALCIUM SULFATE DIHYDRATE | A, E, H | |
| 1108 | CALCIUM SULFIDE | H | Only for use as an active homoeopathic ingredient. |
| 1109 | CALCIUM THREONINATE | A | |
| 1110 | CALENDULA FLOWER DRY | A, E, H | |
| 1111 | CALENDULA FLOWER POWDER | A, H | |
| 1112 | CALENDULA OFFICINALIS | A, E, H | |
| 1113 | CALLERYA RETICULATA | A, H | |
| 1114 | CALLICARPA PEDUNCULATA | A, H | |
| 1115 | CALLISTEPHUS CHINENSIS | A, H | |
| 1116 | CALLITRIS COLUMELLARIS | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1117 | CALLITRIS COLUMELLARIS SUBSP. INTRATROPICA | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1118 | CALLITRIS RHOMBOIDEA | A, H | |
| 1119 | CALLUNA VULGARIS | A, E, H | |

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| 1120 | CALOCHORTUS TOLMIEI | A, H | |
| 1121 | CALTHA PALUSTRIS | A, H | |
| 1122 | CALUMBA ROOT DRY | A, H | |
| 1123 | CALUMBA ROOT POWDER | A, H | |
| 1124 | CALVATIA GIGANTEA | A, E, H | |
| 1125 | CALYCANTHUS FLORIDUS | A, H | |
| 1126 | CALYCANTHUS PRAECOX | A, H | |
| 1127 | CAMELLIA JAPONICA | A, H | |
| 1128 | CAMELLIA OLEIFERA | A, E, H | If Camellia oleifera (seed oil) is used as a solvent, it is restricted to topical or sunscreen preparations for dermal application only. |
| 1129 | CAMELLIA SINENSIS | A, E, H | <p>Caffeine is a mandatory component of Camellia sinensis.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>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.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>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</p> |

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application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'

- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'

- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).

The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is:

- listed in the Register on or after 1 March 2024; or

- released for supply on or after 1 March 2025.

(a) When used in oral medicines, the following warning statements are required on the medicine label:

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| | | | <p>(i) 'In rare cases, <i>Camellia sinensis</i> may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes, or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.'; and</p> <p>(ii) (FOOD) 'To be taken with food.'</p> <p>unless when:</p> <p>(A) the preparation of <i>Camellia sinensis</i> is derived from an aqueous extract and contains 300 mg or less epigallocatechin-3-gallate per maximum recommended daily dose; or</p> <p>(B) <i>Camellia sinensis</i> is used in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>(b) The total concentration of flavour proprietary excipient formulations containing <i>Camellia sinensis</i> must not be more than 5% of the total medicine.</p> |
| 1130 | CAMPHENE | E | <p>Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1131 | CAMPHOLENIC ALDEHYDE | E | <p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than</p> |

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| | | | 5%. |
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| 1132 | CAMPHOR | A, E, H | <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations, the concentration of camphor must be no more than 2.5%.</p> |
| 1133 | CAMPHOR BENZALKONIUM METHOSULFATE | A | <p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the preparation must not be more than 6%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 1134 | CAMPHOR OIL BROWN | A, H | <p>camphor, cineole and saffrole are mandatory components of camphor oil brown.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to</p> |

10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect);
and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect);
and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect);
and

- (NTAKEN) 'Not to be taken'.

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.

When the concentration of cineole

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| | | | <p>in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>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 the restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.</p> <p>When for topical use then the concentration of safrole in a medicine must be no more than 1.0%.</p> <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.</p> |
| 1135 | CAMPBOR OIL WHITE | A, E, H | <p>Camphor and safrole are mandatory components of camphor oil white.</p> <p>In solid and semi solid preparations, the concentration of</p> |

camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of

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| | | | children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When for internal use then the concentration of safrole in a medicine must be no more than 0.1%. When for topical use then the concentration of safrole in a medicine must be no more than 1.0%. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL. |
| 1136 | CAMPSIS GRANDIFLORA | A, H | |
| 1137 | CANADA BALSAM | A, H | |
| 1138 | CANANGA ODORATA | A, E, H | |
| 1139 | CANANGA OIL | A, E, H | |
| 1140 | CANARIUM INDICUM | A, H | Only for use when the plant part is seed and the plant preparation is oil. |
| 1141 | CANARIUM LUZONICUM | A, H | |
| 1142 | CANDELILLA WAX | A, E, H | |
| 1143 | CANDIDA ALBICANS | H | Only for use as an active homoeopathic ingredient. |
| 1144 | CANDIDA UTILIS | A, E, H | When used as an excipient, only for use 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%. |
| 1145 | CANINE MILK | H | Only for use as an active homoeopathic ingredient. |

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| 1146 | CANOLA OIL | A, E, H | Allyl isothiocyanate is a mandatory component of canola oil when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%. |
| 1147 | CANTHARIDES | H | Only available as an active homoeopathic ingredient. |
| 1148 | CANTHAXANTHIN | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 1149 | CAPRIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1150 | CAPROIC ALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1151 | CAPRYLIC ALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a coating solution, a |

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| | | | flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1152 | CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIC TRIGLYCERIDE | E | |
| 1153 | CAPRYLIC/CAPRIC/MYRISTIC/STEARIC TRIGLYCERIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine is not to exceed 3% |
| 1154 | CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE | E | Only for use in topical medicines for dermal application. |
| 1155 | CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. |
| 1156 | CAPRYLOYL GLYCINE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 2% |
| 1157 | CAPRYLOYL SALICYLIC ACID | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must not be more than 0.3%. |

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| 1158 | CAPRYLYL GLYCOL | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2% |
| 1159 | CAPRYLYL METHICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. |
| 1160 | CAPSELLA BURSA-PASTORIS | A, H | |
| 1161 | CAPSICUM | E, H | Only for use as an active homoeopathic or excipient ingredient. |
| 1162 | CAPSICUM ANNUUM | A, E, H | |
| 1163 | CAPSICUM DRY | A, E, H | |
| 1164 | CAPSICUM FRUIT OLEORESIN | A, E | |
| 1165 | CAPSICUM FRUTESCENS | A, E, H | |
| 1166 | CAPSICUM POWDER | A, E, H | |
| 1167 | CARALLUMA ADSCENDENS VAR. FIMBRIATA | A | The plant part must be herb and the plant preparation must be a hydroethanolic extract. |
| 1168 | CARAMEL | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 1169 | CARAPICHEA IPECACUANHA | A, H | Emetine is a mandatory component of Carapichea ipecacuanha. The concentration of emetine in the medicine must not be more than 0.2%. |
| 1170 | CARAWAY DRY | A, H | |
| 1171 | CARAWAY OIL | A, E, H | |

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| 1172 | CARAWAY POWDER | A, H | |
| 1173 | CARBOMER 1342 | E | Only for use as an excipient in topical medicines for dermal application. |
| 1174 | CARBOMER 2001 | E | Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 1% in formulations at pH 7 (approximately neutral) and 0.1% in formulations at a different pH. |
| 1175 | CARBOMER 934 | E | Only for use in topical medicines for dermal application. |
| 1176 | CARBOMER 934P | E | Only for use in topical medicines for dermal application. |
| 1177 | CARBOMER 940 | E | Only for use in topical medicines for dermal application. |
| 1178 | CARBOMER 941 | E | Only for use as an excipient in topical medicines for dermal application. |
| 1179 | CARBOMER 954 | E | Only for use as an excipient in topical medicines for dermal application. |
| 1180 | CARBOMER 980 | E | Only for use as an excipient in topical medicines for dermal application. |
| 1181 | CARBOMER 981 | E | Only for use as an excipient in topical medicines for dermal application. |
| 1182 | CARBOMER COPOLYMER (TYPE | E | Only for use as an excipient in |

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| B) | | | topical medicines for dermal application. |
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| 1183 | CARBOMER HOMOPOLYMER (TYPE B) | E | Only for use as an excipient in topical medicines for dermal application. |
| 1184 | CARBOMER U-10 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. |
| 1185 | CARBON | E, H | Only for use as an active homoeopathic or excipient ingredient. |
| 1186 | CARBON BLACK | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 1187 | CARBON DIOXIDE | E | |
| 1188 | CARDAMOM FRUIT DRY | A, H | |
| 1189 | CARDAMOM FRUIT POWDER | A, E, H | |
| 1190 | CARDAMOM OIL | A, E, H | |
| 1191 | CARDIOSPERMUM HALICACABUM | A, H | |
| 1192 | CARICA PAPAYA | A, E, H | |
| 1193 | CARLINA ACAULIS | A, H | |
| 1194 | CARMELLOSE | E | |
| 1195 | CARMELLOSE CALCIUM | E | |
| 1196 | CARMELLOSE SODIUM | E | |
| 1197 | CARMINE | E | Permitted for use only as a colour for oral and topical use. |
| 1198 | CARMOISINE | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 1199 | CARMOISINE ALUMINIUM | E | Permitted for use only as a colour |

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| | LAKE | | in medicines limited to topical and oral routes of administration. |
| 1200 | CARNAUBA WAX | A, E, H | |
| 1201 | CARNOSINE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%. |
| 1202 | CAROB BEAN EXTRACT | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1203 | CAROB GUM | E | |
| 1204 | CAROB POD | E | |
| 1205 | CAROTENES | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 1206 | CARPINUS BETULUS | A, H | |
| 1207 | CARPINUS CORDATA | A, H | |
| 1208 | CARRAGEENAN | E | |
| 1209 | CARROT | E | |
| 1210 | CARROT SEED OIL | A, E, H | |
| 1211 | CARTHAMUS TINCTORIUS | A, E, H | Carthamus tinctorius (safflower oil) when used as a solvent is restricted to topical or sunscreen preparations for dermal application only. If for oral use, the medicine requires the following warning statement on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect). |

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| 1212 | CARUM CARVI | A, H | |
| 1213 | CARVACROL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1214 | CARVACRYL METHYL ETHER | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1215 | CARVEOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1216 | CARVONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1217 | CARVYL ACETATE | E | Permitted for use only in combination with other permitted |

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| | | | <p>ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1218 | CARYA ILLINOINENSIS | A, H | |
| 1219 | CARYA OVATA | A, H | |
| 1220 | CARYOPHYLLENE OXIDE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1221 | CASCARA DRY | A, H | <p>Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of cascara dry when the route of administration is oral.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) ‘Use in children under 12 years is not recommended’; - (LAX2) ‘Prolonged use may cause serious bowel problems’; and - (LAX3) ‘Do not use when abdominal pain, nausea or |

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| | | | <p>vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' [or words to that effect]. <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'. |
| 1222 | CASCARA POWDER | A, H | <p>Hydroxyanthracene derivatives calculated as cascarioside A is a mandatory component of cascara powder when the route of administration is oral administration.</p> <p>When used in oral medicines, if</p> |

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the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:

- (CHILD3) 'Use in children under 12 years is not recommended';

- (LAX2) 'Prolonged use may cause serious bowel problems'; and

- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).

When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:

- (LAX1) 'Drink plenty of water' (or words to that effect).

When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and

- (LAX4) 'This product may have laxative effect'.

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

- (CHILD3) 'Use in children under 12 years is not

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| | | | recommended’; - (LAX1) ‘Drink plenty of water’ (or words to that effect); and - (LAX2) ‘Prolonged use may cause serious bowel problems’. |
| 1223 | CASCARILLA OIL | A, E, H | The medicine must not contain more than 1 mg of the equivalent dry herbal material per the maximum recommended daily dose. When for use as an excipient ingredient, cascarilla oil must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing cascarilla oil must not be more than 5% of the total medicine. |
| 1224 | CASEIN | E | |
| 1225 | CASHEW NUT | E | |
| 1226 | CASSIA ALATA LEAF EXTRACT | E | Only for use as an excipient ingredient in sunscreens for dermal application and not to be intended for use in the eye. The extraction ratio of the Cassia alata can only be 1:3 in 62.5% glycerine:water. The concentration in the medicine must be no more than 0.0275%. |
| 1227 | CASSIA CINNAMON BARK DRY | A, H | When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%. |
| 1228 | CASSIA CINNAMON BARK POWDER | A, H | When used as an active ingredient, the maximum daily dose of the medicine must contain no more |

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| | | | than 0.001% of coumarin. |
| 1229 | CASSIA FISTULA | A, E, H | <p>Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Cassia fistula when the route of administration is oral.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) ‘Use in children under 12 years is not recommended’; - (LAX2) ‘Prolonged use may cause serious bowel problems’; and - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product’ (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) ‘Drink plenty of water’ (or words to that effect). <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (LAX5) ‘This product contains [name of the herb(s) or the chemical component(s)]’; and - (LAX4) ‘This product may have laxative effect’. <p>When used in oral medicines, if the maximum recommended daily</p> |

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| | | | <p>dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) ‘Use in children under 12 years is not recommended’; - (LAX1) ‘Drink plenty of water’ (or words to that effect); and - (LAX2) ‘Prolonged use may cause serious bowel problems’. <p>When Cassia fistula is for use as an excipient:</p> <ul style="list-style-type: none"> (a) the plant part must be fruit; and (b) must only be included in medicines when in combination with other permitted ingredients as a: <ul style="list-style-type: none"> (i) flavour proprietary excipient formulation when the plant preparation is an extract; and/or (ii) fragrance proprietary excipient formulation when the plant preparation is an essential oil. <p>The total concentration of flavour proprietary excipient formulations containing Cassia fistula must not be more than 5% of the total medicine.</p> <p>The total concentration of fragrance proprietary excipient formulations containing Cassia fistula must not be more than 1% of the total medicine.</p> |
| 1230 | CASSIA OIL | A, E, H | <p>The concentration of Cassia oil in the product must be no more than 2% unless the preparation is for dermal use as a rubefacient, in which case the concentration of cassia oil must be no more than 5%.</p> |

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| 1231 | CASSIE ABSOLUTE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1232 | CASTANEA MOLLISSIMA | A, H | |
| 1233 | CASTANEA SATIVA | A, H | |
| 1234 | CASTOR OIL | A, E | |
| 1235 | CASTOREUM | H | Only permitted for use as an active homoeopathic ingredient. |
| 1236 | CASUARINA EQUISITIFOLIA | A, H | |
| 1237 | CATALPA BIGNONIOIDES | A, H | |
| 1238 | CATALPA OVATA | A, H | |
| 1239 | CATECHU | A, H | |
| 1240 | CATHARANTHUS ROSEUS | A, H | Vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine are mandatory components of Catharanthus roseus. The concentration of vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%. |
| 1241 | CAULIFLOWER | E | |
| 1242 | CAULOPHYLLUM THALICTROIDES | A, E, H | |
| 1243 | CAUSTICUM | H | Only for use as an active homoeopathic ingredient. |
| 1244 | CEANOTHUS AMERICANUS | A, H | |
| 1245 | CEDAR LEAF OIL | A, E, H | |

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| 1246 | CEDARWOOD OIL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1247 | CEDARWOOD OIL TERPENES | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1248 | CEDARWOOD OIL VIRGINIA | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1249 | CEDRENOL | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1250 | CEDRENYLACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> |

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| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1251 | CEDROL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1252 | CEDRUS ATLANTICA | A, E, H | |
| 1253 | CEDRUS ATLANTICA WOOD OIL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1254 | CEDRUS DEODARA | A, H | |
| 1255 | CEDRUS LIBANI | H | Only for use as an active homoeopathic ingredient. |
| 1256 | CEDRYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1257 | CEDRYL METHYL ETHER | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1258 | CELERY SEED DRY | A, E, H | |

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| 1259 | CELERY SEED OIL | A, E, H | |
| 1260 | CELERY SEED POWDER | A, H | |
| 1261 | CELLACEFATE | E | |
| 1262 | CELLULASE | A | Must be derived from <i>Trichoderma longibrachiatum</i> only. |
| 1263 | CELLULOSE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1264 | CELOSIA ARGENTEA | A, H | |
| 1265 | CELOSIA ARGENTEA L. VAR. CRISTATA | A, H | |
| 1266 | CENTAUREA CYANUS | A, E, H | |
| 1267 | CENTAURIUM ERYTHRAEA | A, H | |
| 1268 | CENTELLA ASIATICA | A, E, H | |
| 1269 | CENTELLA ASIATICA MERISTEM CELL CULTURE | E | Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.05%. |
| 1270 | CENTIPEDA CUNNINGHAMII | A, E, H | |
| 1271 | CENTIPEDA MINIMA | A, H | |
| 1272 | CEPHALANOPSIS SEGETUM | A, H | |
| 1273 | CERAMIDE 1 | E | Only for use in topical medicines for dermal application. |
| 1274 | CERAMIDE 2 | E | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%. |

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| 1275 | CERAMIDE 3 | E | Only for use in topical medicines for dermal application. |
| 1276 | CERAMIDE 6 II | E | Ceramide 6 II must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin or in the eye. The concentration in the medicine must be no more than 0.011%. |
| 1277 | CERATONIA SILIQUA | A, E, H | |
| 1278 | CERATOSTIGMA WILLMOTTIANUM | A, H | |
| 1279 | CERESIN | E | Only for use in topical medicines for dermal application. |
| 1280 | CESTRUM LATIFOLIUM | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The plant part must be leaf and must be a water extract. The concentration must be no more than 0.5%. |
| 1281 | CETEARETH-12 | E | Only for use in topical medicines for dermal application. |
| 1282 | CETEARETH-2 | E | Only for use in topical medicines for dermal application. |
| 1283 | CETEARETH-20 | E | Only for use in topical medicines for dermal application. |
| 1284 | CETEARETH-25 | E | Only for use in topical medicines for dermal application. |

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| 1285 | CETEARETH-30 | E | Only for use in topical medicines for dermal application. |
| 1286 | CETEARETH-33 | E | Only for use as an excipient ingredient for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%. Residual levels of 1,4-dioxane oxide (and related substances) are to be kept below the level of detection. |
| 1287 | CETEARYL GLUCOSIDE | E | Only for use in topical medicines for dermal application. |
| 1288 | CETEARYL ISONONANOATE | E | Only for use in topical medicines for dermal application. |
| 1289 | CETEARYL NONANOATE | E | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must not be more than 5%. |
| 1290 | CETEARYL OCTANOATE | E | Only for use in topical medicines for dermal application. |
| 1291 | CETETH-10 | E | Only for use in topical medicines for dermal application. |
| 1292 | CETETH-2 | E | Only for use in topical medicines for dermal application. |
| 1293 | CETETH-24 | E | Only for use in topical medicines for dermal application. |
| 1294 | CETETH-5 | E | Only for use in topical medicines for dermal application. |

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| 1295 | CETOMACROGOL 1000 | E | Only for use in topical medicines for dermal application. |
| 1296 | CETOMACROGOL 1000 PHOSPHATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%. |
| 1297 | CETOMACROGOL 500 PHOSPHATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%. |
| 1298 | CETOSTEARYL ALCOHOL | E | |
| 1299 | CETOSTEARYL ALCOHOL/COCO-GLUCOSIDE COMPLEX | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5.0 % |
| 1300 | CETRARIA ISLANDICA | A, H | |
| 1301 | CETRIMONIUM BROMIDE | E | Only for use in topical medicines for dermal application. |
| 1302 | CETRIMONIUM CHLORIDE | E | Only for use in topical medicines for dermal application. |
| 1303 | CETYL ACETATE | E | Only for use in topical medicines for dermal application. |
| 1304 | CETYL ALCOHOL | E | Only for use in topical medicines for dermal application. |

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| 1305 | CETYL DIMETHICONE COPOLYOL | E | Only for use in topical medicines for dermal application. |
| 1306 | CETYL DIMETICONE | E | Only for use in topical medicines for dermal application. |
| 1307 | CETYL DIMETICONE/BIS- VINYLDIMETICONE CROSSPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%. |
| 1308 | CETYL ESTERS WAX | E | Only for use in topical medicines for dermal application. |
| 1309 | CETYL HYDROXYETHYLCELLULOSE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. |
| 1310 | CETYL LACTATE | E | Only for use in topical medicines for dermal application. |
| 1311 | CETYL OCTANOATE | E | Only for use in topical medicines for dermal application. |
| 1312 | CETYL PALMITATE | E | Only for use in topical medicines for dermal application. |
| 1313 | CETYL PHOSPHATE | E | Only for use in topical medicines for dermal application. |
| 1314 | CETYL-PG HYDROXYETHYL PALMITAMIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 8%. |

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| 1315 | CETYLPIRIDINIUM CHLORIDE | A, E | <p>Only permitted for use in medicines containing 5% or less of quaternary ammonium compounds.</p> <p>When used as an excipient ingredient, only for use in topical medicines for dermal application.</p> <p>When used as an active ingredient:</p> <p>(a) permitted for use only in medicated throat lozenges;</p> <p>(b) the medicine must not contain more than 2 milligrams of cetylpyridinium chloride per lozenge;</p> <p>(c) the maximum recommended daily dose of the medicine must not provide more than 24 milligrams of cetylpyridinium chloride; and</p> <p>(d) the medicine label must specify that the medicine is only to be used for 7 days (or less).</p> |
| 1316 | CHAENOMELES LAGENARIA | A, H | |
| 1317 | CHAENOMELES SPECIOSA | A, H | |
| 1318 | CHALK | A, E | <p>When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.</p> |
| 1319 | CHAMAECYPARIS LAWSONIANA | A, H | |
| 1320 | CHAMAELIRIUM LUTEUM | A, H | |
| 1321 | CHAMAEMELUM NOBILE | A, E, H | |
| 1322 | CHAMOMILE FLOWER DRY | A, E, H | |
| 1323 | CHAMOMILE OIL ENGLISH | A, E, H | |
| 1324 | CHAMOMILE OIL GERMAN | A, E, H | |

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| 1325 | CHANGIUM SMYRNIOIDES | A, H | |
| 1326 | CHEIRANTHUS CHEIRI | A, H | |
| 1327 | CHELIDONIUM MAJUS | A, E, H | When the medicine is for oral or sublingual use, the following warning statement is required on the medicine label: (CELAND1) 'In rare cases, Chelidonium majus may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain or dark urine.' |
| 1328 | CHELONE GLABRA | A, H | |
| 1329 | CHENOPODIUM ALBUM | A, H | |
| 1330 | CHENOPODIUM VULVARIA | A, H | |
| 1331 | CHERRY | E | |
| 1332 | CHERRY DISTILLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1333 | CHESTNUT SWEET | E, H | |
| 1334 | CHICKEN COMB EXTRACT | A | |
| 1335 | CHICKEN STERNUM CARTILAGE POWDER | A | Only to be used in a medicine where Capsugel Australia Pty Ltd (Client ID 43174), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 3 July 2025. The route of administration for medicines that contain chicken sternum cartilage powder must be |

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| | | | <p>limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 40 mg of chicken sternum cartilage powder.</p> <p>The following warning statement (or words to that effect) is required on the medicine label:</p> <p>- (ADULT) 'Adults only'.</p> |
| 1336 | CHIMAPHILA UMBELLATA | A, H | <p>Beta-arbutin is a mandatory component of Chimaphila umbellata.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>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%.</p> |
| 1337 | CHIONANTHUS VIRGINICA | A, H | |
| 1338 | CHLORELLA | E | <p>Iodine is a mandatory component of Chlorella.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the</p> |

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| | | | medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 1339 | CHLORELLA PYRENOIDOSA | E | |
| 1340 | CHLORELLA VULGARIS | A, E | Iodine is a mandatory component of <i>Chlorella vulgaris</i> . Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 1341 | CHLORHEXIDINE ACETATE | E | Only for use in topical medicines for dermal application. |
| 1342 | CHLORHEXIDINE GLUCONATE | E | Only for use in topical medicines for dermal application. |
| 1343 | CHLOROBUTANOL HEMIHYDRATE | E | Only for use in topical preparations for dermal application. The concentration in the medicine must be no more than 0.5%. |
| 1344 | CHLOROCRESOL | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%. |
| 1345 | CHLOROFORM | E | The residual solvent limit must be no more than 0.6 mg per recommended daily dose and the concentration in the medicine must be no more than 0.006%. |
| 1346 | CHLOROPHYLL | A, E | Only for use as a colour in oral |

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| | | | and topical medicines. |
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| 1347 | CHLOROPHYLL-COPPER COMPLEXES | E | Only for use as a colour in oral and topical medicines. |
| 1348 | CHLOROPHYLLIN-COPPER COMPLEX | E | Only for use as a colour in oral and topical medicines. |
| 1349 | CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE | E | Only for as a colour in oral and topical medicines. |
| 1350 | CHLOROXYLENOL | E | Only for use in topical medicines for dermal application. |
| 1351 | CHLORPHENESIN | E | Only for use in topical medicines for dermal application. |
| 1352 | CHOCOLATE BROWN HT | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 1353 | CHOLESTEROL | E, H | Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations. |
| 1354 | CHOLESTERYL HYDROXYSTEARATE | E | Only for use in topical medicines for dermal application. |
| 1355 | CHOLESTERYL MACADAMIATE | E | Only for use in topical medicines for dermal application. |
| 1356 | CHOLESTERYL/BEHENYL/OCTYLDODECYL LAUROYL GLUTAMATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%. |
| 1357 | CHOLETH-24 | E | Only for use in topical medicines for dermal application. |

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| 1358 | CHOLINE BITARTRATE | A, E | |
| 1359 | CHOLINE DIHYDROGEN CITRATE | A | Only for use in oral medicines. |
| 1360 | CHONDRODENDRON TOMETOSUM | A, H | The concentration of equivalent dry Chondrodendron tomentosum in the product must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 1361 | CHONDRUS CRISPUS | A, E, H | Iodine is a mandatory component of Chondrus crispus. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 1362 | CHONDRUS DRY | A, E, H | Iodine is a mandatory component of Chondrus dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 1363 | CHONDRUS EXTRACT | A, E, H | Iodine is a mandatory component of Chondrus extract. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the |

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| | | | medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. |
| 1364 | CHROMIC CHLORIDE HEXAHYDRATE | A, H | <p>When used as an active ingredient in a preparation for mineral supplementation, chromium is a mandatory component of chromic chloride hexahydrate.</p> <p>The amount of chromium in the active ingredient should be calculated based on the molecular weight of chromic chloride hexahydrate.</p> <p>The maximum recommended daily dose must provide 50 micrograms or less of chromium from organic sources (i.e. chromium picolinate, chromium nicotinate and high chromium yeast).</p> |
| 1365 | CHROMIUM NICOTINATE | A | <p>Chromium is a mandatory component of chromium nicotinate.</p> <p>The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources.</p> <p>Chromium nicotinate is considered to be an organic form of chromium.</p> |
| 1366 | CHROMIUM PICOLINATE | A | <p>Chromium is a mandatory component of Chromium picolinate.</p> <p>The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources.</p> <p>Chromium picolinate is considered to be an organic form of chromium.</p> |

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| 1367 | CHRYSANTHEMUM BALSAMITA | A, H | |
| 1368 | CHRYSANTHEMUM INDICUM | A, H | |
| 1369 | CHRYSANTHEMUM LEUCANTHEMUM | A, H | |
| 1370 | CHRYSANTHEMUM SINENSE | A, H | |
| 1371 | CHRYSOPOGON ZIZANIOIDES | A, E, H | |
| 1372 | CHRYSOSPORIUM PRUINOSUM | A, H | |
| 1373 | CIBOTIUM BAROMETZ | A, H | |
| 1374 | CICHORIUM INTYBUS | A, E, H | |
| 1375 | CICUTA VIROSA | A, H | The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 1376 | CINCHONA BARK DRY | A, H | Quinidine and quinine are mandatory components of Cinchona bark dry. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL. |
| 1377 | CINCHONA BARK POWDER | A, H | Quinidine and quinine are mandatory components of Cinchona bark powder. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL. |
| 1378 | CINCHONA OFFICINALIS | A, H | Quinidine and quinine are mandatory components of Cinchona officinalis. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL. |

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| 1379 | CINCHONA PUBESCENS | A, H | <p>Quinidine and quinine are mandatory components of Cinchona pubescens.</p> <p>The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.</p> |
| 1380 | CINEOLE | E | <p>In liquid preparations when the concentration of cineole in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, 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 also have a child resistant closure.</p> |
| 1381 | CINNAMALDEHYDE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a</p> |

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| | | | | medicine must be no more 1%. |
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| 1382 | CINNAMIC ACID | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> | |
| 1383 | CINNAMOMUM CAMPHORA | A, E, H | <p>Camphor, cineole and safrole are mandatory components of Cinnamomum camphora.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations or distillates and the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres and the following warning statements must be included on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; <p>and</p> <ul style="list-style-type: none"> - Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist'. <p>In essential oil preparations or distillates, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the</p> | |

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nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container.

In essential oil preparations or distillates, 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.

In essential oil preparations or distillates, 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.

In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect);
and

- (NTAKEN) 'Not to be taken'.

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.

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| | | | <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container.</p> <p>When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.</p> <p>When for uses other than internal use, the concentration of safrole in a medicine must be no more than 1.0%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p> |
| 1384 | CINNAMOMUM CASSIA | A, E | <p>Cassia oil is a mandatory component of Cinnamomum cassia if the plant preparation is an essential oil, distillate, fixed oil or infused oil.</p> <p>The concentration of Cassia oil in the medicine must be no more than 2%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p> |
| 1385 | CINNAMOMUM VERUM | A, E, H | <p>When used as an active ingredient coumarin is a mandatory component of Cinnamomum verum and the concentration of coumarin in the medicine must be no more than 0.001%.</p> <p>Cinnamon bark oil is a mandatory component of Cinnamomum verum when the plant part is bark and the plant preparation is</p> |

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| | | | <p>essential oil, distillate, fixed oil or infused oil.</p> <p>The concentration of cinnamon bark oil in the medicine must be no more than 2%.</p> <p>Cinnamon leaf oil is a mandatory component of <i>Cinnamomum verum</i> when the plant part is leaf.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but no more than 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the container must be fitted with a restricted flow insert.</p> |
| 1386 | CINNAMON BARK OIL | A, E, H | The concentration of cinnamon bark oil in the product must be no more than 2%. |

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| | | | When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%. |
| 1387 | CINNAMON DRY | A, H | <p>Cinnamon bark oil is a mandatory component of cinnamon dry.</p> <p>The concentration of cinnamon bark oil in the product must be no more than 2%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p> |
| 1388 | CINNAMON LEAF OIL | A, E, H | <p>When the concentration of cinnamon leaf oil in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 mL.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, the medicine must have a child resistant closure and restricted flow insert fitted on the container and requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect). - (NTAKEN) 'Not to be taken'. <p>When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, the container must be fitted with a restricted flow insert and requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of |

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| | | | <p>children' (or words to that effect). - (NTAKEN) 'Not to be taken'. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p> |
| 1389 | CINNAMON POWDER | A, E, H | <p>Cinnamon bark oil is a mandatory component of cinnamon powder. The concentration of cinnamon bark oil in the product must be no more than 2%. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p> |
| 1390 | CINNAMYL ACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1391 | CINNAMYL ALCOHOL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1392 | CINNAMYL BUTYRATE | E | <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p> |

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| | | | 5%. Permitted for use only in combination with other permitted ingredients as a flavour. |
| 1393 | CINNAMYL CINNAMATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1394 | CINNAMYL FORMATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1395 | CINNAMYL ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1396 | CINNAMYL ISOVALERATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1397 | CINNAMYL PROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than |

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| | | | 1%. |
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| 1398 | CINOXATE | A | <p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 6%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 1399 | CIS-2-METHYL-4-PROPYL-1,3-OXATHIANE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1400 | CIS-3-HEXEN-1-OL | E | <p>cis-3-Hexen-1-ol must only be included in medicines when in combination with other permitted ingredients as a flavour or fragrance proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing cis-3-hexen-1-ol must not be more than 5% of the total medicine.</p> |

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| | | | The total concentration of fragrance proprietary excipient formulations containing cis-3-hexen-1-ol must not be more than 1% of the total medicine. |
| 1401 | CIS-3-HEXENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1402 | CIS-3-HEXENYL 2-METHYLBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1403 | CIS-3-HEXENYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1404 | CIS-3-HEXENYL BENZOATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1405 | CIS-3-HEXENYL BUTYRATE | E | Permitted for use only in |

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| | | | <p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1406 | CIS-3-HEXENYL FORMATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1407 | CIS-3-HEXENYL HEXANOATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1408 | CIS-3-HEXENYL ISOBUTYRATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1409 | CIS-3-HEXENYL ISOVALERATE | E | <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>Permitted for use only in combination with other permitted</p> |

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| | | | ingredients as a flavour or a fragrance. |
| 1410 | CIS-3-HEXENYL LACTATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1411 | CIS-3-HEXENYL METHYL CARBONATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1412 | CIS-3-HEXENYL SALICYLATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1413 | CIS-3-HEXENYL TIGLATE | E | Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 1414 | CIS-4-HEPTENAL | E | Permitted for use only in combination with other permitted ingredients as a flavour. |

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| | | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1415 | CIS-6-NONEN-1-AL | E | | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1416 | CIS-6-NONENOL | E | | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1417 | CIS-BETA-OCIMENE | E | | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1418 | CIS-HEXAHYDROCUMINYL ALCOHOL | E | | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 1419 | CIS-JASMONE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1420 | CISTANCHE DESERTICOLA | A, H | |
| 1421 | CISTANCHE SALSIA | A, H | |
| 1422 | CISTUS LADANIFER | A, E, H | |
| 1423 | CITRAL | E | |
| 1424 | CITRAL DIETHYL ACETAL | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1425 | CITRAL DIMETHYL ACETAL | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1426 | CITRIC ACID | A, E | <p>Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When used as an active ingredient in preparations for topical use, the medicine requires the following</p> |

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| | | | <p>warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect) - (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect) - (IRRIT) 'If irritation develops, discontinue use.' - (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.' - (CHILD3) 'Use in children under 12 years is not recommended' |
| 1427 | CITRIC ACID DIHYDRATE | A, E | <p>Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect) - (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect) - (IRRIT) 'If irritation develops, discontinue use.' - (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.' - (CHILD3) 'Use in children under |

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| | | | 12 years is not recommended' |
| 1428 | CITRIC ACID MONOHYDRATE | A, E | <p>Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect) - (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect) - (IRRIT) 'If irritation develops, discontinue use.' - (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.' - (CHILD3) 'Use in children under 12 years is not recommended.' |
| 1429 | CITRIC AND FATTY ACID ESTERS OF GLYCEROL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1430 | CITROL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p> |

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| 1431 | CITRON | E | | |
| 1432 | CITRONELLA OIL | A, E, H | Medicines for topical use containing citronella oil require the following warning statement on the medicine label: - (CITRON) 'Contains citronella oil'. | |
| 1433 | CITRONELLA TERPENES | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. | |
| 1434 | CITRONELLAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. | |
| 1435 | CITRONELLIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. | |
| 1436 | CITRONELLOL | E | Permitted for use only: | |

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| | | | <p>(a) in topical medicines for dermal application; and</p> <p>(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> |
| 1437 | CITRONELLYL ACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1438 | CITRONELLYL BUTYRATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1439 | CITRONELLYL FORMATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |

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| 1440 | CITRONELLYL ISOBUTYRATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1441 | CITRONELLYL NITRILE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1442 | CITRONELLYL OXYACETALDEHYDE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1443 | CITRONELLYL PROPIONATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1444 | CITRONELLYL TIGLATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total</p> |

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| | | | fragrance concentration in a medicine must be no more than 1%. |
| 1445 | CITRULLINE | A | Only permitted for use in medicines: (a) limited to oral routes of administration; and (b) when the maximum recommended daily dose does not provide more than 6 g of citrulline. |
| 1446 | CITRULLUS COLOCYNTHIS | H | Citrullus colocynthis can only be included in medicines for oral use when the dilution of the mother tincture is 10,000 fold (4X) or more. |
| 1447 | CITRULLUS VULGARIS | A, H | |
| 1448 | CITRUS AURANTIFOLIA | A, E, H | When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.5% or less of citrus aurantifolia oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin. |
| 1449 | CITRUS AURANTIUM | A, E, H | Oxedrine is a mandatory component of Citrus aurantium when intended for internal use. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg. When the plant preparation is oil or distillate, the warning statement |

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| | | | (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 1.4% or less of citrus aurantium oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin. |
| 1450 | CITRUS BIOFLAVONOIDS EXTRACT | A, E, H | |
| 1451 | CITRUS CHACHIENSIS | A, H | |
| 1452 | CITRUS EXTRACT | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1453 | CITRUS FIBRE | E | |
| 1454 | CITRUS LIMETTA | A, H | When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.5% or less of citrus limetta oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin. |
| 1455 | CITRUS LIMON | A, E, H | Oxedrine is a mandatory component of Citrus limon when intended for internal use. |

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| | | | <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p> <p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.05% or less of citrus limon oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p> |
| 1456 | CITRUS MAXIMA | A, H | |
| 1457 | CITRUS MEDICA | A, E, H | <p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.05% or less of citrus medica oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p> |
| 1458 | CITRUS OIL DISTILLED | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |

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| 1459 | CITRUS OIL TERPENES AND TERPENOIDS | E | <p>Citrus oil terpenes and terpenoids must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing citrus oil terpenes and terpenoids must not be more than 1% of the total medicine.</p> |
| 1460 | CITRUS RETICULATA | A, E, H | <p>Oxedrine is a mandatory component of Citrus reticulata when intended for internal use.</p> <p>The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.</p> |
| 1461 | CITRUS SINENSIS | A, E, H | <p>Oxedrine is a mandatory component of Citrus sinensis when intended for internal use.</p> <p>The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.</p> |
| 1462 | CITRUS SINENSIS PEEL MOLASSES EXTRACT | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1463 | CITRUS UNSHIU | A, E, H | <p>Oxedrine is a mandatory component of Citrus unshiu when intended for internal use.</p> <p>The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.</p> |
| 1464 | CITRUS X PARADISI | A, E, H | |

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| 1465 | CITRUS X WILSONII | A, H | |
| 1466 | CIVET | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1467 | CIVET ABSOLUTE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1468 | CIVET SYNTHETIC | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1469 | CIVETONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1470 | CLARY OIL | A, E, H | |
| 1471 | CLEMATIS ARMANDII | A, H | |
| 1472 | CLEMATIS CHINENSIS | A, E, H | |
| 1473 | CLEMATIS RECTA | A, H | |
| 1474 | CLEMATIS VITALBA | A, H | |
| 1475 | CLERODENDRUM TRICHOTOMUM | A, H | |
| 1476 | CLINOPODION POLYCEPHALUM | A, H | |

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| 1477 | CLINOPODIUM NEPETA SUBSP. GLANDULOSUM | A, H | |
| 1478 | CLIVER HERB DRY | A, H | |
| 1479 | CLIVER HERB POWDER | A, H | |
| 1480 | CLOVE BUD OIL | A, E, H | When the total concentration of clove oils (including clove bud oil, clove leaf oil, and clove stem oil) in the medicine is more than 25%: (a) the nominal capacity of the container must not be more than 25 mL; (b) a restricted flow insert must be fitted on the container; (c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'; and (d) When the nominal capacity of the container is more than 15 mL, a child resistant closure must also be fitted on the container. |
| 1481 | CLOVE DRY | A, E, H | |
| 1482 | CLOVE LEAF OIL | A, E, H | When the total concentration of clove oils (including clove bud oil, clove leaf oil, and clove stem oil) in the medicine is more than 25%: (a) the nominal capacity of the container must not be more than 25 mL; (b) a restricted flow insert must be fitted on the container; (c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'; and (d) When the nominal capacity of |

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| | | | the container is more than 15 mL, a child resistant closure must also be fitted on the container. |
| 1483 | CLOVE OIL TERPENES | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1484 | CLOVE POWDER | A, E, H | |
| 1485 | CLOVE STEM OIL | A, E, H | When the total concentration of clove oils (including clove bud oil, clove leaf oil, and clove stem oil) in the medicine is more than 25%: (a) the nominal capacity of the container must not be more than 25 mL; (b) a restricted flow insert must be fitted on the container; (c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'; and (d) When the nominal capacity of the container is more than 15 mL, a child resistant closure must also be fitted on the container. |
| 1486 | CLUPEA HARENGUS LIPID EXTRACT | A | Only for use in oral medicines. The maximum recommended daily dose must not provide more than 2750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids. |
| 1487 | CNICUS BENEDICTUS | A, H | |

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| 1488 | CNICUS JAPONICUS | A, H | |
| 1489 | CNIDIUM MONNIERI | A, H | |
| 1490 | CNIDIUM OFFICINALE | A, H | |
| 1491 | COBALTOUS NITRATE HEXAHYDRATE | H | Only for use as an active homoeopathic ingredient. |
| 1492 | COCAMIDE DEA | E | Only for use in topical medicines for dermal application. |
| 1493 | COCAMIDE MEA | E | Only for use in topical medicines for dermal application. |
| 1494 | COCAMIDOPROPYL BETAINAMIDE MEA CHLORIDE | E | Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye. The concentration in the medicine must be no more than 1%. |
| 1495 | COCAMIDOPROPYL BETAINE | E | Only for topical, mucous membrane (buccal mucosa) and dental use and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be: a) no more than 1% in leave on medicines b) no more than 15% in wash on /wash off medicines c) 1.2% for buccal mucosa and dental medicines. Levels of impurities 3-dimethylaminopropylamine (DMAPA) and amidoamine (dimethylaminopropylcocoamide; AA) must be controlled to below the level of detection. |
| 1496 | COCCOLOBIA UVIFERA | A, H | |
| 1497 | COCCULUS ORBICULATUS | A, H | |
| 1498 | COCHINEAL | E, H | Only for use as an active |

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| | | | homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines. |
| 1499 | COCHLEARIA OFFICINALIS | A, H | |
| 1500 | COCILLANA DRY | A, H | |
| 1501 | COCILLANA POWDER | A, H | |
| 1502 | COCO-BETAINE | E | Only for use in topical medicines for dermal application. |
| 1503 | COCO-CAPRYLATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration is to be no more than 12.5% in the medicine. |
| 1504 | COCO-GLUCOSIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.025% |
| 1505 | COCO-OCTANOATE/DECANOATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. |
| 1506 | COCOA EXTRACT | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1507 | COCOA POWDER | A, E, H | |
| 1508 | COCOGLYCERIDES | E | |
| 1509 | COCONUT | E | |
| 1510 | COCONUT ACID | E | Only for use in topical medicines for dermal application. |

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| 1511 | COCONUT OIL | A, E, H | |
| 1512 | COCOS NUCIFERA | A, E, H | |
| 1513 | COD-LIVER OIL | A, E | <p>Vitamin A and coilecalciferol are mandatory components of Cod-liver oil.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</p> |

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| | | | When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D. |
| 1514 | CODONOPSIS LANCEOLATA | A, H | |
| 1515 | CODONOPSIS PILOSULA | A, H | |
| 1516 | CODONOPSIS TANGSHEN | A, H | |
| 1517 | COFFEA ARABICA | A, E, H | <p>Caffeine is a mandatory component of Coffea arabica.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>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.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity |

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| | | | <p>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.'</p> <p>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</p> <p>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:</p> <p>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</p> <p>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</p> |
| 1518 | COFFEA CANEPHORA | A, E, H | <p>Caffeine is a mandatory component of Coffea canephora.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>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.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use</p> |

or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine.'

- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'

- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional

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| | | | before taking with other medicines' (or words to that effect). |
| 1519 | COFFEE | E, H | <p>Caffeine is a mandatory component of coffee.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>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.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of |

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| | | | <p>caffeine.'</p> <p>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</p> <p>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:</p> <p>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</p> <p>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</p> |
| 1520 | COFFEE OIL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1521 | COFFEE SOLID EXTRACT | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1522 | COGNAC OIL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total</p> |

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| | | | flavour concentration in a medicine must be no more than 5%. |
| 1523 | COGNAC OIL GREEN | A, E, H | |
| 1524 | COGNAC OIL WHITE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1525 | COIX LACHRYMA-JOBI | A, H | |
| 1526 | COLA ACUMINATA | A, E, H | Caffeine is a mandatory component of Cola acuminata. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period. When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral |

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| | | | <p>application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' <p>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:</p> <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect). |
| 1527 | COLA NITIDA | A, E, H | <p>Caffeine is a mandatory component of Cola nitida.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>When for internal use or oral application, the maximum</p> |

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recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.

When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'

- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:

- (CAFFLMT) 'Limit the use of caffeine-containing products'

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| | | | (including tea and coffee) when taking this product.' |
| | | | - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect). |
| 1528 | COLCHICUM AUTUMNALE | H | Only for use as an active homoeopathic ingredient. The total concentration of Colchicum autumnale in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |
| 1529 | COLECALCIFEROL | A, E | When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D. |
| 1530 | COLLAGEN | E | |
| 1531 | COLLINSONIA CANADENSIS | A, H | |
| 1532 | COLLOIDAL ANHYDROUS SILICA | A, E, H | Only for use when the route of administration is other than inhalation. |
| 1533 | COLOPHONY | A, E, H | |
| 1534 | COMMIPHORA HABESSINICA | A, H | |
| 1535 | COMMIPHORA KATAF | A, H | |
| 1536 | COMMIPHORA MYRRHA | A, E, H | |
| 1537 | COMMON INDIAN COBRA | H | Only for use as an active homoeopathic ingredient. |
| 1538 | CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES | A | Only for oral use. |
| 1539 | CONCENTRATED SQUID OMEGA-3 TRIGLYCERIDES | A | Only for oral use. 'Concentrated squid omega-3-triglycerides' must be obtained from species of the order Teuthida of the class Cephalopoda AND be in combination with other |

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| | | | <p>ingredients in the preparation AND be presented in a therapeutic dosage form for therapeutic use.</p> <p>The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.</p> |
| 1540 | CONIFER GREEN NEEDLE COMPLEX | A | <p>Only for topical and oral use. Must be made by petroleum ether extraction of needles of the conifer species <i>Pinus sylvestris</i> (Scotch Pine) and <i>Picea abies</i> (Norwegian Spruce).</p> |
| 1541 | CONIFER PHYTOSTEROL COMPLEX | A | |
| 1542 | CONIOSELINUM TATARICUM | A, H | |
| 1543 | CONIUM MACULATUM | H | <p>Only for use as an active homoeopathic ingredient.</p> <p>The homoeopathic potency of <i>Conium maculatum</i> in the final medicine must be 12X or greater.</p> |
| 1544 | CONVALLARIA MAJALIS | A, H | <p>The concentration of equivalent dry <i>Convallaria majalis</i> in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.</p> |
| 1545 | CONYZA CANADENSIS | A, H | |
| 1546 | COPAIBA OIL | A, E, H | |
| 1547 | COPAIFERA LANGSDORFFII | A, E, H | |
| 1548 | COPERNICIA CERIFERA | A, E, H | |
| 1549 | COPOVIDONE | E | |
| 1550 | COPPER | H | <p>Only for use as an active homoeopathic ingredient.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than</p> |

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| | | | 5%. |
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| 1551 | COPPER (II) ASPARTATE | A, H | <p>Copper is a mandatory component of copper (II) aspartate.</p> <p>The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of copper (II) aspartate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p> |
| 1552 | COPPER (II) GLYCINATE | A, H | <p>Copper is a mandatory component of copper (II) glycinate.</p> <p>The percentage of copper from copper (II) glycinate should be calculated based on the molecular weight of Copper (II) glycinate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p> |
| 1553 | COPPER (II) LYSINATE | A, H | <p>Copper is a mandatory component of copper (II) lysinate.</p> <p>The percentage of copper from copper (II) lysinate should be calculated based on the molecular weight of Copper (II) lysinate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p> |
| 1554 | COPPER ACETYL TYROSINATE METHYLSILANOL | E | <p>Only for use in topical medicines for dermal application.</p> |
| 1555 | COPPER CHLOROPHYLL | E | <p>Permitted for use only in combination with other permitted</p> |

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| | | | <p>ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1556 | COPPER CHLOROPHYLLIN | E | Only for use as a colour in oral and topical medicines. |
| 1557 | COPPER GLUCONATE | A, E | <p>Copper is a mandatory component of copper gluconate.</p> <p>The percentage of copper from copper gluconate should be calculated based on the molecular weight of copper gluconate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> |
| 1558 | COPPER TRIPEPTIDE-1 | E | <p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 3%.</p> |
| 1559 | COPTIS CHINENSIS | A, H | |
| 1560 | COPTIS JAPONICA | A, H | |
| 1561 | CORALLINA OFFICINALIS | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine is to be no more than 1%.</p> |
| 1562 | CORDYCEPS SINENSIS | A, E, H | Must not contain material of animal origin such as insect larvae. |
| 1563 | CORIANDER DRY | A, H | |

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| 1564 | CORIANDER OIL | A, E, H | |
| 1565 | CORIANDER POWDER | A, H | |
| 1566 | CORIANDRUM SATIVUM | A, E, H | |
| 1567 | CORMUS DOMESTICA | A, H | |
| 1568 | CORN GLYCERIDES | E | |
| 1569 | CORN SILK DRY | A, H | |
| 1570 | CORN SILK POWDER | A, H | |
| 1571 | CORN SYRUP | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1572 | CORN SYRUP SOLIDS | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1573 | CORNUS FLORIDA | A, H | |
| 1574 | CORNUS OFFICINALIS | A, H | |
| 1575 | CORTISONE ACETATE | H | Only available as an active homoeopathic ingredient. |
| 1576 | CORYDALIS AMBIGUA | A, E, H | |
| 1577 | CORYDALIS BUNGEANA | A, H | |
| 1578 | CORYDALIS CAVA | A, H | |
| 1579 | CORYDALIS FABACEA | A, H | |
| 1580 | CORYDALIS FORMOSA | A, H | |
| 1581 | CORYDALIS TURTSCHANINOVII | A, H | |
| 1582 | CORYLUS AMERICANA | A, H | |
| 1583 | CORYLUS AVELLANA | A, H | |
| 1584 | CORYMBIA CITRIODORA | A, E, H | Cineole is a mandatory component of <i>Corymbia citriodora</i> . In liquid preparations when the concentration of cineole OR the |

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concentration of oil or distillate in the preparation is more than 25%:

- a) the nominal capacity of the container must be no more than 25 millilitres;
- b) a restricted flow insert must be fitted on the container; and
- c) the container must include the following warning statements on the medicine label:
 - (CHILD) 'Keep out of reach of children' (or words to that effect); and
 - (NTAKEN) 'Not to be taken'.

In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.

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| 1585 | CORYMBIA FICIFOLIA | A, H | <p>Cineole is a mandatory component of <i>Corymbia ficifolia</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none">a) the nominal capacity of the container must be no more than 25 millilitres;b) a restricted flow insert must be fitted on the container; andc) the container must include the following warning statements on the medicine label:<ul style="list-style-type: none">- (CHILD) 'Keep out of reach of children' (or words to that effect); and- (NTAKEN) 'Not to be taken'. <p>In liquid preparations, when the concentration of cineole OR the</p> |
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| | | | concentration of oil or distillate 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 also have a child resistant closure. |
| 1586 | COSMOS BIPINNATUS | A, H | |
| 1587 | COSTUS ROOT OIL | A, H | |
| 1588 | COSTUS SPICATUS | A, H | |
| 1589 | COTTONSEED OIL | A, E, H | |
| 1590 | COUCH GRASS RHIZOME DRY | A, H | |
| 1591 | COUCH GRASS RHIZOME POWDER | A, H | |
| 1592 | COUMARIN | E, H | <p>Only for use as an active homoeopathic ingredient or excipient ingredient.</p> <p>The concentration of coumarin in the medicine must not be more than 0.001%.</p> <p>When used as an excipient:</p> <p>(a) must only be used in topical medicines for dermal application; and</p> <p>(b) the label of the medicine must specify that the product should only be used by adults.</p> |
| 1593 | CRANBERRY | E | |
| 1594 | CRATAEGUS CUNEATA | A, E, H | |
| 1595 | CRATAEGUS GERMANICA | A, H | |
| 1596 | CRATAEGUS LAEVIGATA | A, E, H | |
| 1597 | CRATAEGUS MONOGYNA | A, E, H | |
| 1598 | CRATAEGUS PINNATIFIDA | A, E, H | |
| 1599 | CRATEVA MAGNA | A, E, H | |
| 1600 | CREATINE | A, E | |
| 1601 | CREATINE MONOHYDRATE | A, E | |
| 1602 | CREATINE PHOSPHATE | A, E | |
| 1603 | CREATININE | E | Only for use in topical medicines for dermal application and not for |

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| | | | <p>use in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.2%.</p> |
| 1604 | CREOSOL | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1605 | CREOSOTE | H | <p>Only for use as an active homoeopathic ingredient.</p> |
| 1606 | CRESOL | E | <p>Only for use as a preservative in topical medicines.</p> <p>The concentration of phenols (including cresols and xylenols and any other homologue of phenol) boiling below 220 degrees centigrade must be no more than 3%.</p> |
| 1607 | CRITHMUM MARITIMUM WHOLE PLANT EXTRACT | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.00341%.</p> |
| 1608 | CROCUS SATIVUS | A, E, H | <p>When Crocus sativus is used as an excipient:</p> <p>(a) the ingredient must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation;</p> |

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| | | | (b) the plant part must be stigma and/or style; (c) the plant preparation must be fresh or dry; and (d) the total concentration of flavour proprietary excipient formulations containing the ingredient must not be more than 5% of the total medicine. |
| 1609 | CROSCARMELLOSE SODIUM | E | |
| 1610 | CROSPVIDONE | E | |
| 1611 | CROTON CASCARILLA | A, H | The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 1612 | CROTON ELUTERIA | A, H | The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 1613 | CRYPTOMERIA JAPONICA | A, H | |
| 1614 | CUBEB OIL | A, H | |
| 1615 | CUBEBENE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1616 | CUCUMBER | E | |
| 1617 | CUCUMIS MELO | A, H | |
| 1618 | CUCUMIS SATIVUS | A, E, H | |
| 1619 | CUCURBITA MAXIMA | A, E, H | |
| 1620 | CUCURBITA MOSCHATA | A, H | |
| 1621 | CUCURBITA PEPO | A, E, H | |
| 1622 | CULLEN CORYLIFOLIUM | A, H | |
| 1623 | CUMIC ALCOHOL | E | Permitted for use only in combination with other permitted |

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| | | | | ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1624 | CUMIN OIL | A, E, H | | |
| 1625 | CUMINALDEHYDE | E | | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1626 | CUMINUM CYMINUM | A, H | | |
| 1627 | CUMINYL NITRILE | E | | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1628 | CUPRESSUS ARIZONICA | A, H | | |
| 1629 | CUPRESSUS FUNEBRIS | A, E, H | | |
| 1630 | CUPRESSUS SEMPERVIRENS | A, E, H | | |
| 1631 | CUPRIC ACETATE MONOHYDRATE | H | | Only for use as an active homoeopathic ingredient. |
| 1632 | CUPRIC ARSENITE | H | | Only for use as an active homoeopathic ingredient. |
| 1633 | CUPRIC CITRATE | A, E, H | | When for oral or sublingual use, copper is a mandatory component of cupric citrate. The percentage of copper from cupric citrate should be calculated |

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| | | | <p>based on the molecular weight of cupric citrate.</p> <p>The medicine must not contain more than 750 micrograms of copper from cupric citrate per the recommended daily dose or the medicine must not contain more than 1.86 milligrams of cupric citrate per the recommended daily dose.</p> |
| 1634 | CUPRIC CITRATE HEMIPENTAHYDRATE | A, E, H | <p>When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate.</p> <p>The percentage of copper from cupric citrate hemipentahydrate should be calculated based on the molecular weight of cupric citrate hemipentahydrate.</p> <p>The medicine must not contain more than 750 micrograms of copper from cupric citrate hemipentahydrate per the recommended daily dose OR the medicine must not contain more than 2.13 milligrams of cupric citrate hemipentahydrate per the recommended daily dose.</p> |
| 1635 | CUPRIC OXIDE | A, E, H | <p>When for oral or sublingual use, copper is a mandatory component of cupric oxide.</p> <p>The percentage of copper from cupric oxide should be calculated based on the molecular weight of cupric oxide.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> |

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| 1636 | CUPRIC SULFATE | A, E, H | <p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate.</p> <p>The percentage of copper from cupric sulfate should be calculated based on the molecular weight of cupric sulfate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> |
| 1637 | CUPRIC SULFATE MONOHYDRATE | A, E, H | <p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate monohydrate.</p> <p>The percentage of copper from cupric sulfate monohydrate should be calculated based on the molecular weight of cupric sulfate monohydrate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> <p>When used topically, cupric sulfate is a mandatory component of cupric sulfate monohydrate.</p> |
| 1638 | CUPRIC SULFATE PENTAHYDRATE | A, E, H | <p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate pentahydrate.</p> <p>The percentage of copper from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.</p> <p>When for internal use the maximum daily dose must not</p> |

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| | | | <p>contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> <p>When used topically cupric sulfate is a mandatory component of cupric sulfate pentahydrate.</p> <p>The percentage of cupric sulfate from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.</p> |
| 1639 | CURCULIGO ORCHIOIDES | A, H | |
| 1640 | CURCUMA AROMATICA | A, H | <p>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. <p>(a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label: 'In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.'</p> <p>(b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione in the medicine must not provide more than:</p> <ul style="list-style-type: none"> (i) 36 mg for children from 2-3 years (inclusive); (ii) 48 mg for children from 4-11 years (inclusive); and |

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| | | | (iii) 123 mg for children from 12-17 years (inclusive). (c) Not permitted for use in children aged below 2 years. |
| 1641 | CURCUMA LONGA | A, E, H | <p>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. <p>(a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label: 'In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.'</p> <p>(b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione in the medicine must not provide more than:</p> <ul style="list-style-type: none"> (i) 36 mg for children from 2-3 years (inclusive); (ii) 48 mg for children from 4-11 years (inclusive); and (iii) 123 mg for children from 12-17 years (inclusive). <p>(c) Not permitted for use in children aged below 2 years.</p> |
| 1642 | CURCUMA ZANTHORRHIZA | A, H | <p>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> - listed in the Register on or after |

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| | | | <p>1 March 2024; or</p> <p>- released for supply on or after 1 March 2025.</p> <p>(a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label: ‘In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.’</p> <p>(b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione in the medicine must not provide more than:</p> <p>(i) 36 mg for children from 2-3 years (inclusive);</p> <p>(ii) 48 mg for children from 4-11 years (inclusive); and</p> <p>(iii) 123 mg for children from 12-17 years (inclusive).</p> <p>(c) Not permitted for use in children aged below 2 years.</p> |
| 1643 | CURCUMA ZEDOARIA | A, H | <p>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:</p> <p>- listed in the Register on or after 1 March 2024; or</p> <p>- released for supply on or after 1 March 2025.</p> <p>(a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label: ‘In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have</p> |

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| | | | <p>yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.’</p> <p>(b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione in the medicine must not provide more than:</p> <p>(i) 36 mg for children from 2-3 years (inclusive);</p> <p>(ii) 48 mg for children from 4-11 years (inclusive); and</p> <p>(iii) 123 mg for children from 12-17 years (inclusive).</p> <p>(c) Not permitted for use in children aged below 2 years.</p> |
| 1644 | CURCUMIN | A, E, H | <p>When for excipient use, only permitted for use as a colour in topical and oral medicines.</p> <p>The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none">- listed in the Register on or after 1 March 2024; or- released for supply on or after 1 March 2025. <p>(a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label:</p> <p>‘In very rare cases, curcumin may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.’</p> <p>(b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-</p> |

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| | | | 3,5-dione in the medicine must not provide more than: (i) 36 mg for children from 2-3 years (inclusive); (ii) 48 mg for children from 4-11 years (inclusive); and (iii) 123 mg for children from 12-17 years (inclusive). (c) Not permitted for use in children aged below 2 years. |
| 1645 | CUSCUTA EPITHYMUM | A, H | |
| 1646 | CUSCUTA EUROPAEA | A, H | |
| 1647 | CUSCUTA HYGROPHILAE | A, H | |
| 1648 | CUSCUTA RACEMOSA | A, H | |
| 1649 | CUSPARIA FEBRIFUGA | A, H | |
| 1650 | CYAMOPSIS TETRAGONOLOBA | A, E, H | |
| 1651 | CYANOCOBALAMIN | A, E, H | |
| 1652 | CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE | E | For dental use only in proprietary ingredients. Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%. |
| 1653 | CYATHULA OFFICINALIS | A, H | |
| 1654 | CYCLAMEN ALDEHYDE | E | Only for use as an excipient ingredient in topical medicines. |
| 1655 | CYCLAMEN PURPURASCENS | A, H | |
| 1656 | CYCLOCARYA PALIURUS LEAF EXTRACT DRY | A | Only to be used in a medicine where Infinitus (China) Company Ltd (Client ID 81208), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. |

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| | | | <p>This paragraph ceases to be a requirement for this ingredient after 25 October 2025.</p> <p>The route of administration for medicines that contain <i>Cyclocarya paliurus</i> leaf extract dry must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 2 g of <i>Cyclocarya paliurus</i> leaf extract dry.</p> <p>The recommend duration of use for a medicine containing <i>Cyclocarya paliurus</i> leaf extract dry must be limited to 12 weeks or less.</p> <p>The following warning statements (or words to the same effect) are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'. |
| 1657 | CYCLOHEXADECENONE-8 | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1658 | CYCLOHEXANE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1659 | CYCLOHEXANE, 1-ETHENYL-1-METHYL-2-(1-METHYLETHENYL)-4-(1- | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> |

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| | METHYLETHYL)-, DIDEHYDRO DERIV. | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1660 | CYCLOHEXANEETHANOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1661 | CYCLOHEXYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1662 | CYCLOHEXYL BUTYRATE | E | Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 1663 | CYCLOHEXYL PHENETHYL ETHER | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |

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| 1664 | CYCLOHEXYL SALICYLATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1665 | CYCLOHEXYLETHYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 1666 | CYCLOMETHICONE | E | Only for use as an excipient ingredient in topical medicines. |
| 1667 | CYCLOPENTADECANONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1668 | CYDONIA OBLONGA | A, H | |
| 1669 | CYMBOPOGON FLEXUOSUS | A, E, H | When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon flexuosus and the concentration of aldehydes calculated as citral in the medicine must not be more than 5%. |
| 1670 | CYMBOPOGON MARTINI | A, H | When for topical use, aldehydes calculated as citral is a mandatory |

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| | | | component of Cymbopogon martini and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%. |
| 1671 | CYMBOPOGON NARDUS | A, H | When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon nardus and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%. |
| 1672 | CYMBOPOGON SCHOENANTHUS | A, E, H | When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon schoenanthus and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%. |
| 1673 | CYNANCHUM ATRATUM | A, H | |
| 1674 | CYNANCHUM STAUNTONII | A, E, H | |
| 1675 | CYNARA SCOLYMUS | A, E, H | |
| 1676 | CYNODON DACTYLON | A, E, H | |
| 1677 | CYNOMORIUM COCCINEUM SUBSP. SONGARICUM | A, H | |
| 1678 | CYPERUS LONGUS | A, H | |
| 1679 | CYPERUS ROTUNDUS | A, H | |
| 1680 | CYPRESS OIL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1681 | CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS | A, H | |
| 1682 | CYSTEINE | A | The maximum recommended daily dose must not contain more than 450 mg of cysteine. |

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| | | | When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose. |
| 1683 | CYSTEINE HYDROCHLORIDE | A | <p>The maximum recommended daily dose must contain no more than 585 mg of cysteine hydrochloride.</p> <p>When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p> |
| 1684 | CYSTEINE HYDROCHLORIDE MONOHYDRATE | A, E | <p>When used as an excipient, permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient and the total flavour proprietary excipient formulation concentration in a medicine must not be more than 5%.</p> <p>The maximum recommended daily dose must contain no more than 652 mg of cysteine hydrochloride monohydrate.</p> <p>When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p> |
| 1685 | CYSTINE | A | <p>The maximum recommended daily dose must contain no more than 450 mg of cystine.</p> <p>When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg</p> |

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| | | | cysteine per maximum recommended daily dose. |
| 1686 | CYTISUS SCOPARIUS | A, H | Sparteine is a mandatory component of Cytisus scoparius. The concentration of Sparteine in the medicine must be no more than 0.001%. |
| 1687 | D-ALPHA-TOCOPHEROL | A, E | |
| 1688 | D-ALPHA-TOCOPHERYL ACETATE | A, E, H | |
| 1689 | D-ALPHA-TOCOPHERYL ACID SUCCINATE | A, E | |
| 1690 | D-ALPHA-TOCOPHERYL PHOSPHATES | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3%. |
| 1691 | D-BORNEOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1692 | D-CARVONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1693 | D-FENCHONE | E | Permitted for use only in |

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| | | | combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1694 | D-LIMONENE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1695 | D-PULEGONE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. The concentration of d-pulegone in the medicine must not be more than 4%. |
| 1696 | D-RIBOSE-L-CYSTEINE | A | Only for use in oral medicines. Cysteine is a mandatory component of D-Ribose-L-Cysteine. The medicine must provide no more than 450 mg of cysteine per maximum recommended daily dose. |
| 1697 | DACTYLIS GLOMERATA | A, H | |
| 1698 | DACTYLORHIZA INCARNATA SUBSP. INCARNATA | A, H | |
| 1699 | DAEMONOROPS DRACO | A, E, H | |

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| 1700 | DAHLIA PINNATA | A, H | |
| 1701 | DALBERGIA ODORIFERA | A, H | |
| 1702 | DAMIANA LEAF POWDER | A | |
| 1703 | DANDELION LEAF DRY | A, H | |
| 1704 | DANDELION LEAF POWDER | A, H | |
| 1705 | DANDELION ROOT DRY | A, H | |
| 1706 | DANDELION ROOT POWDER | A, H | |
| 1707 | DAPHNE GENKWA | A, H | |
| 1708 | DAPHNE MEZEREUM | A, H | The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material. |
| 1709 | DATURA STRAMONIUM | A, H | Only for use in oral medicines. Alkaloids calculated as hyoscyamine is a mandatory component of Datura stramonium. The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. |
| 1710 | DAUCUS CAROTA | A, E, H | |
| 1711 | DAVANA OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1712 | DEA-OLETH-3 PHOSPHATE | E | Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye. The concentration in the medicine |

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| | | | <p>must be no more than 1%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (EYE) 'Avoid contact with eyes' - (EYE2) 'May be irritant to the eyes' (or words to that effect). |
| 1713 | DECAHYDRO-1,1,7-TRIMETHYL-3A,7-METHANO-3AH-CYCLOPENTACYCLOOCT-3-YL FORMATE | E | <p>Decahydro-1,1,7-trimethyl-3a,7-methano-3ah-cyclopentacyclooct-3-yl formate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing decahydro-1,1,7-trimethyl-3a,7-methano-3ah-cyclopentacyclooct-3-yl formate must not be more than 1% of the total medicine.</p> |
| 1714 | DECAHYDRO-2,2,6,6,7,8,8-HEPTAMETHYL-2H-INDENO(4,5-B) FURAN | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1715 | DECAHYDRO-BETA-NAPHTHYLACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1716 | DECAHYDRO-BETA-NAPHTHYLFORMATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a</p> |

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| | | | medicine must be no more than 1%. |
| 1717 | DECAHYDROSPIRO(FURAN-2(3H),5'-(4,7)METHANO(5H)INDENE) | E | Permitted for use only in combination with other permitted ingredients as a fragrance. The total fragrance concentration in a medicine must be no more than 1%. |
| 1718 | DECALACTONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1719 | DECANAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1720 | DECANAL DIMETHYL ACETAL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1721 | DECARBOXY CARNOISINE DIHYDROCHLORIDE | E | Only for use in topical medicines for dermal application and not to |

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| | | | be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05. |
| 1722 | DECENAL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1723 | DECYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1724 | DECYL ALCOHOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1725 | DECYL GLUCOSIDE | E | Only for use in topical medicines for dermal application. |
| 1726 | DECYL OLEATE | E | Only for use in topical medicines for dermal application. |

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| 1727 | DECYLENE GLYCOL | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.5%.</p> |
| 1728 | DEER ANTLER CARTILAGE | H | <p>Only for use as an active homoeopathic ingredient.</p> |
| 1729 | DEER VELVET ANTLER POWDER | A | <p>Medicines that contain 'deer velvet antler powder' as the therapeutically active ingredient are subject to the following conditions:</p> <ul style="list-style-type: none"> a) the medicines are for oral use only; b) the antlers (including the velvet) are sourced only from red deer (<i>Cervus elaphus</i>), elk/wapiti (<i>Cervus canadensis</i>), or a crossbreed of these species; c) the deer are sourced only from farmed stock bred and raised in New Zealand; d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time; e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time. |
| 1730 | DEER VELVET ANTLER SLICE | A | <p>Medicines that contain 'deer velvet antler slice' as the therapeutically active ingredient are subject to the following conditions:</p> |

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| | | | <p>a) the medicines are for oral use only;</p> <p>b) the antlers (including the velvet) are sourced only from red deer (<i>Cervus elaphus</i>), elk/wapiti (<i>Cervus canadensis</i>), or a crossbreed of these species;</p> <p>c) the deer are sourced only from farmed stock bred and raised in New Zealand;</p> <p>d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time;</p> <p>e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.</p> |
| 1731 | DEERTONGUE ABSOLUTE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1732 | DEHYDROACETIC ACID | E | <p>Only for use in topical medicines for dermal application.</p> |
| 1733 | DEHYDROMENTHOFUROLACT ONE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1734 | DEHYDROXANTHAN GUM | E | <p>Only for use in topical medicines</p> |

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| | | | for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. |
| 1735 | DELPHINIUM STAPHISAGRIA | A, H | The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%. |
| 1736 | DELTA-DAMASCONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1737 | DELTA-DECALACTONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1738 | DELTA-DODECALACTONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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| 1739 | DELTA-NONALACTONE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1740 | DELTA-OCTALACTONE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1741 | DELTA-TETRADECALACTONE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1742 | DELTA-TOCOPHEROL | E | |
| 1743 | DELTA-UNDECALACTONE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than</p> |

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| 1744 | DEMINERALISED FISH PROTEOGLYCAN EXTRACT | A | |
| 1745 | DENATONIUM BENZOATE | E | |
| 1746 | DENDROBIUM NOBILE | A, H | |
| 1747 | DESCURAINIA SOPHIA | A, H | |
| 1748 | DESMODIUM STYRACIFOLIUM | A, H | |
| 1749 | DEVIL'S CLAW TUBER DRY | A, H | |
| 1750 | DEVIL'S CLAW TUBER POWDER | A, H | |
| 1751 | DEXPANTHENOL | A, E | |
| 1752 | DEXTRAN 20 | E | <p>Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.3%.</p> |
| 1753 | DEXTRAN 40 | A, E | |
| 1754 | DEXTRATES | E | |
| 1755 | DEXTRIN | E | |
| 1756 | DEXTRIN PALMITATE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p> |
| 1757 | DHA/EPA RICH SCHIZOCHYTRIUM ALGAL OIL | A | <p>Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are mandatory components of DHA/EPA rich schizochytrium algal oil.</p> <p>Only for use in oral medicines when in combination with other active or excipient ingredients.</p> <p>The ratio of DHA to EPA must be 2:1.</p> |
| 1758 | DI-C12-13 ALKYL MALATE | E | Only for use in topical medicines |

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| | | | for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. |
| 1759 | DI-C12-15 ALKYL FUMARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. |
| 1760 | DI-N-PROPYL ISOCINCHOMERONATE | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%. |
| 1761 | DI-PPG-3 MYRISTYL ETHER ADIPATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%. |
| 1762 | DIACETIN | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1763 | DIACETYL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a |

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| | | | <p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1764 | DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1765 | DIACETYLATED MONOGLYCERIDES | E | Permitted for use only in combination with other permitted ingredients as a coating solution. |
| 1766 | DIAMMONIUM LAURYL SULFOSUCCINATE | E | Only for use as an excipient ingredient in topical medicines. |
| 1767 | DIANTHUS SUPERBUS | A, H | |
| 1768 | DIAZOLIDINYL UREA | E | Only for use in topical medicines for dermal application. |
| 1769 | DIBASIC MAGNESIUM CITRATE TETRAHYDRATE | A | Only for use in oral medicines. |
| 1770 | DIBASIC MAGNESIUM PHOSPHATE TRIHYDRATE | A, E, H | <p>Magnesium is a mandatory component of dibasic magnesium phosphate trihydrate.</p> <p>The percentage of magnesium from dibasic magnesium phosphate trihydrate should be calculated based on the molecular weight of dibasic magnesium phosphate trihydrate.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum</p> |

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| | | | <p>recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p> |
| 1771 | DIBASIC POTASSIUM PHOSPHATE | A, E, H | <p>When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> |
| 1772 | DIBASIC POTASSIUM PHOSPHATE TRIHYDRATE | A, E, H | <p>When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate trihydrate.</p> |

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| | | | <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> |
| 1773 | DIBASIC SODIUM PHOSPHATE | A, E, H | <p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> |
| 1774 | DIBASIC SODIUM PHOSPHATE DIHYDRATE | A, E, H | <p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dihydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> |
| 1775 | DIBASIC SODIUM PHOSPHATE DODECAHYDRATE | A, E, H | <p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dodecahydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> |

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| | | | 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. |
| 1776 | DIBASIC SODIUM PHOSPHATE HEPTAHYDRATE | A, E, H | When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate heptahydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. |
| 1777 | DIBASIC SODIUM PHOSPHATE MONOHYDRATE | A, E, H | When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate monohydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. |
| 1778 | DIBENZYL KETONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |

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| 1779 | DIBUTYL ADIPATE | E | Only for use in topical medicines for dermal application. |
| 1780 | DIBUTYL SEBACATE | E | |
| 1781 | DIBUTYLAMINE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%. |
| 1782 | DICAPRYLYL CARBONATE | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%. |
| 1783 | DICAPRYLYL ETHER | E | Only for use in topical medicines for dermal application. |
| 1784 | DICAPRYLYL MALEATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. |
| 1785 | DICETYL PHOSPHATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%. |
| 1786 | DICHLOROBENZYL ALCOHOL | E | |
| 1787 | DICHLOROMETHANE | E | The concentration in the medicine must be no more than 0.06%. The residual solvent limit for Dichloromethane is 6 mg per recommended daily dose. |

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| 1788 | DICTAMNUS ALBUS | A, H | |
| 1789 | DICTAMNUS DASYCARPUS | A, H | |
| 1790 | DICYCLOHEXYL DISULFIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1791 | DIEFFENBACHIA SEGUINE | H | Only for use as an active homoeopathic ingredient. |
| 1792 | DIETHANOLAMINE | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%. |
| 1793 | DIETHYL CITRACONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1794 | DIETHYL HYDROGEN 2-HYDROXYPROPANE-1,2,3-TRICARBOXYLATE | E | Diethyl hydrogen 2-hydroxypropane-1,2,3-tricarboxylate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing diethyl hydrogen 2-hydroxypropane-1,2,3-tricarboxylate must not be more than 1% of the total medicine. |
| 1795 | DIETHYL MALONATE | E | Permitted for use only in |

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| | | | <p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1796 | DIETHYL PHTHALATE | E | |
| 1797 | DIETHYLAMINE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 1798 | DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE | A | <p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 1799 | DIETHYLAMINOMETHYLCOUM ARIN | E | <p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 0.1%.</p> |

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| 1800 | DIETHYLDIMETHYL-2-CYCLOHEXENONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1801 | DIETHYLENE GLYCOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1802 | DIETHYLENE GLYCOL MONOETHYL ETHER | E | Only for use in topical medicines for dermal application. |
| 1803 | DIETHYLHEXYL CARBONATE | E | Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3%. |
| 1804 | DIETHYLHEXYL SEBACATE | E | Only for use in topical medicines for dermal application. |
| 1805 | DIETHYLHEXYL SYRINGYLIDENEMALONATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. |
| 1806 | DIETHYLHEXYL-2,6-NAPHTHALATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. |

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| | | | The medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect). |
| 1807 | DIETHYLTOLUAMIDE | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 20%. The medicine requires the following warning statement on the medicine label: - (DEET) 'WARNING: May be dangerous; particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.' |
| 1808 | DIGITALIS LEAF DRY | A, H | The concentration of Digitalis leaf dry in the product must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 1809 | DIGITALIS LEAF POWDER | A, H | The concentration of Digitalis leaf powder in the product must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 1810 | DIGITALIS PURPUREA | A, H | The concentration of equivalent dry Digitalis purpurea in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 1811 | DIGLYCOL/CHDM/ISOPHTHALATES/SIP COPOLYMER | E | Only for use in topical medicines for dermal application. |
| 1812 | DIHEXYL FUMARATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total |

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| | | | fragrance concentration in a medicine must be no more than 1%. |
| 1813 | DIHYDRO JASMONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1814 | DIHYDRO TERPINYLACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1815 | DIHYDRO-ALPHA-TERPINEOL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1816 | DIHYDRO-BETA-IONONE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1817 | DIHYDRO-ISOJASMONE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total |

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| | | | fragrance concentration in a medicine must be no more than 1%. |
| 1818 | DIHYDROACTINIDIOLIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1819 | DIHYDROAMBRETTOLIDE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1820 | DIHYDROCAPSIATE | A | The route of administration for medicines that contain dihydrocapsiate must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 9 mg dihydrocapsiate. The following warning statements (or words to the same effect) are required on the medicine label: - (ADULT) 'Adults only'; and - (PREGNT) 'Not recommended for use by pregnant and lactating women'. |
| 1821 | DIHYDROCARVYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

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| 1822 | DIHYDROCOUMARIN | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1823 | DIHYDROCUMINYL ALCOHOL | E | <p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p> |
| 1824 | DIHYDROEUGENOL | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1825 | DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p> |
| 1826 | DIHYDROINDENYL-2,4-DIOXANE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |

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| 1827 | DIHYDROLINALOOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1828 | DIHYDROMYRCENOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1829 | DIHYDROMYRCENYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1830 | DIHYDROXYACETONE | E | Only for use in topical medicines for dermal application. |
| 1831 | DIISOPROPYL ADIPATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%. |
| 1832 | DIISOPROPYL SEBACATE | E | Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye. |

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| | | | The concentration in the medicine must be no more than 10%. |
| 1833 | DIISOSTEARYL DIMER DILINOLEATE | E | Only for use in topical medicines for dermal application. |
| 1834 | DILAURYL THIODIPROPIONATE | E | Only for use in topical medicines for dermal application. |
| 1835 | DILL HERB OIL | A, E, H | |
| 1836 | DILL SEED OIL | A, E, H | |
| 1837 | DIMER DISTEARYLTRICARBONATE | E | Only for use in topical medicines for dermal application and not to be used in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. |
| 1838 | DIMETHICONE 12500 | E | |
| 1839 | DIMETHICONE 4000 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. |
| 1840 | DIMETHICONE CROSSPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%. |
| 1841 | DIMETHICONE SILYLATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. |
| 1842 | DIMETHICONE/METHICONE | E | Only for use in topical medicines |

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| | COPOLYMER | | for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. |
| 1843 | DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%. |
| 1844 | DIMETHYL 3-CYCLOHEXENE-1- CARBOXALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1845 | DIMETHYL ANTHRANILATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1846 | DIMETHYL BENZYL CARBINOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1847 | DIMETHYL BENZYL CARBINYL ACETATE | E | Permitted for use only in combination with other permitted |

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| | | | <p>ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1848 | DIMETHYL BENZYL CARBINYL BUTYRATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 1849 | DIMETHYL BENZYL CARBINYL ISOBUTYRATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1850 | DIMETHYL PHENYLETHYL CARBINOL | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 1851 | DIMETHYL PHTHALATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than</p> |

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| | | | 1%. |
| 1852 | DIMETHYL POLYSILOXANE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1853 | DIMETHYL SUCCINATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1854 | DIMETHYL SULFIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1855 | DIMETHYL SULFONE | A | Only for use in oral and topical medicines. |
| 1856 | DIMETHYL SULFOXIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1857 | DIMETHYLACETAL | E | Permitted for use only in combination with other permitted |

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| | | | ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1858 | DIMETHYLCYCLOHEXYLETHOXY ISOBUTYLPROPANOATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1859 | DIMETHYLGLYCINE HYDROCHLORIDE | A | Only for use in oral medicines. |
| 1860 | DIMETHYLOL DIMETHYL HYDANTOIN | E | Only for use in topical medicines for dermal application. |
| 1861 | DIMETICONE 1.5 | E | Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must not be more than 23%. |
| 1862 | DIMETICONE 10 | E | |
| 1863 | DIMETICONE 100 | E | Only for use in topical medicines for dermal application. |
| 1864 | DIMETICONE 1000 | E | |
| 1865 | DIMETICONE 1510 | E | Permitted for use only in combination with other permitted ingredients as a printing ink. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1% |
| 1866 | DIMETICONE 2 | E | Only for use in topical medicines for dermal application and not to be included in medicines for use |

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| | | | in the eye or on damaged skin. The concentration in the medicine must be no more than 9.602%. |
| 1867 | DIMETICONE 20 | E | Only for use in topical medicines for dermal application. |
| 1868 | DIMETICONE 200 | E | Only for use in topical medicines for dermal application. |
| 1869 | DIMETICONE 30 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. |
| 1870 | DIMETICONE 350 | E | Only for use in topical and oral medicines. When used orally, the maximum daily dose must be no more than 7.5mg. |
| 1871 | DIMETICONE 360 | E | Only for use in topical medicines for dermal application. |
| 1872 | DIMETICONE 450 | E | Only for use in topical medicines for dermal application. |
| 1873 | DIMETICONE 5 | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%. |
| 1874 | DIMETICONE 50 | E | Only for use in topical medicines for dermal application. |
| 1875 | DIMETICONE 5000 | E | Only for use in topical medicines for dermal application. |
| 1876 | DIMETICONE 6 | E | Only for use in topical medicines |

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| | | | for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. |
| 1877 | DIMETICONE COPOLYOL | E | Only for use in topical medicines for dermal application. |
| 1878 | DIMETICONE COPOLYOL PHOSPHATE | E | Only for use in topical medicines for dermal application. |
| 1879 | DIMETICONE CROSSPOLYMER-3 | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%. |
| 1880 | DIMETICONE/PEG-10/15 CROSSPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. |
| 1881 | DIMETICONOL | E | Only for use in topical medicines for dermal application. |
| 1882 | DIMETICONOL STEARATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. |
| 1883 | DIMETICONOL/PROPYLSILSESQ UIOXANE/SILICATE 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 damaged skin. The concentration in the medicine |

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| must not be more than 10%. | | | |
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| 1884 | DIMOCARPUS LONGAN | A, H | |
| 1885 | DIOCTYL ADIPATE | E | Only for use in topical medicines for dermal application. |
| 1886 | DIOCTYL MALEATE | E | Only for use in topical medicines for dermal application. |
| 1887 | DIOCTYL SUCCINATE | E | Only for use in topical medicines for dermal application. |
| 1888 | DIOCTYL TEREPHTHALATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1889 | DIOLAMINE C8-18 PERFLUOROALKYLETHYL PHOSPHATE | E | Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.7% |
| 1890 | DIOLAMINE CETYL PHOSPHATE | E | Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye. |
| 1891 | DIOSCOREA COLLETTII | A, H | |
| 1892 | DIOSCOREA COLLETTII VAR. HYPOGLAUCA | A, H | |
| 1893 | DIOSCOREA JAPONICA | A, H | |
| 1894 | DIOSCOREA OPPOSITIFOLIA | A, H | |
| 1895 | DIOSCOREA POLYSTACHYA | A, H | |

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| 1896 | DIOSCOREA SEPTEMLOBA | A, H | |
| 1897 | DIOSCOREA VILLOSA | A, E, H | |
| 1898 | DIOSPYROS KAKI | A, E, H | |
| 1899 | DIOXYBENZONE | A | <p>Only for use as an active ingredient in sunscreens for dermal application.</p> <p>The concentration in the medicine must be no more than 3%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 1900 | DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRA TE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.5%.</p> |
| 1901 | DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TE TRAIOSTEARATE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p> |
| 1902 | DIPENTAERYTHRITYL TRI- POLYHYDROXYSTEARATE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p> |
| 1903 | DIPHENYL DIMETHICONE | E | <p>Only for use in topical medicines for dermal application.</p> |

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| 1904 | DIPHENYL METHANE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1905 | DIPHENYL OXIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1906 | DIPOTASSIUM GLYCYRRHIZATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%. |
| 1907 | DIPROPIONYL | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1908 | DIPROPYLENE GLYCOL | E | Only for use in topical medicines for dermal application. |
| 1909 | DIPROPYLENE GLYCOL DIBENZOATE | 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 4.2%. |
| 1910 | DIPROPYLENE GLYCOL SALICYLATE | E | Only for use in topical medicines for dermal application. |
| 1911 | DIPSACUS ASPER | A, H | |
| 1912 | DIPSACUS JAPONICUS | A, H | |
| 1913 | DIPTERYX ODORATA | A, E, H | When used as an active ingredient coumarin is a mandatory component of <i>Dipteryx odorata</i> and the concentration of coumarin in the medicine must be no more than 0.001%. |
| 1914 | DISODIUM ASCORBYL SULFATE | E | Only for use in topical medicines for dermal application. |
| 1915 | DISODIUM COCOAMPHODIACETATE | E | Only for use in topical medicines for dermal application. |
| 1916 | DISODIUM COCOAMPHODIPROPIONATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. |
| 1917 | DISODIUM DIMETICONE COPOLYOL SULFOSUCCINATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 14%. |
| 1918 | DISODIUM EDETATE | E | Edetic acid is a mandatory component of disodium edetate. The total concentration of edetic acid in the medicine must not be more than 0.25%. |
| 1919 | DISODIUM ETHYLENE | E | Only for use in topical medicines |

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| | DICOCAMIDE PEG-15 DISULFATE | | for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1%. |
| 1920 | DISODIUM GUANYLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1921 | DISODIUM INOSINATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1922 | DISODIUM LAURIL SULFOSUCCINATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 0.35%. |
| 1923 | DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. |
| 1924 | DISODIUM NADH | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%. |
| 1925 | DISODIUM OLEAMIDO PEG-2 | E | Only for use in topical medicines |

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| | SULFOSUCCINATE | | for dermal application and not to be included in medicines for use in the eye. The concentration in the medicine must be no more than 1%. |
| 1926 | DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE | A | Only for use as an active ingredient in sunscreens for dermal application. The concentration in the medicine must be no more than 10%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 1927 | DISODIUM PYROPHOSPHATE | E | Disodium pyrophosphate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing disodium pyrophosphate must not be more than 5% of the total medicine. The maximum recommended daily dose of the medicine must not provide more than 2.4 g of phosphorus. The following statement (or words to the same effect) is required on the medicine label: - (PHOS) 'Contains phosphorus'. |
| 1928 | DISODIUM RICINOLEAMIDO MEA-SULFOSUCCINATE | E | Only for use in topical medicines for dermal application and not to |

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| | | | be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. |
| 1929 | DISODIUM RUTINYL DISULFATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%. |
| 1930 | DISODIUM STEAROYL GLUTAMATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. |
| 1931 | DISPERSIBLE CELLULOSE | E | |
| 1932 | DISTARCH PHOSPHATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. |
| 1933 | DISTEARDIMONIUM HECTORITE | E | Only for use in topical medicines for dermal application and not to be included for medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. |
| 1934 | DISTEARETH-6 DIMONIUM CHLORIDE | E | Only for use in topical medicines for dermal application. |
| 1935 | DISTEARYL PHTHALIC ACID AMIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. |

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| 1936 | DISTEARYLDIMONIUM CHLORIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. |
| 1937 | DIVINYLDIMETHICONE/DIMETHICONE COPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%. |
| 1938 | DL-ALPHA-TOCOPHEROL | A, E | |
| 1939 | DL-ALPHA-TOCOPHERYL ACETATE | A, E, H | |
| 1940 | DL-ALPHA-TOCOPHERYL ACID SUCCINATE | A, E, H | |
| 1941 | DL-BORNEOL | E | |
| 1942 | DL-LIMONENE | E | Only for use in topical medicines for dermal application. |
| 1943 | DL-THREONINE | A, E | |
| 1944 | DOCOSAHEXAENOIC ACID (DHA)-RICH OIL DERIVED FROM MICROALGAE SCHIZOCHYTRIUM SP. | A | Only for use in oral medicines and must be present in combination with other ingredients. |
| 1945 | DOCUSATE SODIUM | E | |
| 1946 | DODECAHYDRO-3A,6,6,9A- TETRAMETHYLNAPHTHO(2,1- B)FURAN | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1947 | DODECANENITRILE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total |

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| | | | fragrance concentration in a medicine must be no more than 1%. |
| 1948 | DODECENE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%. |
| 1949 | DODECYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1950 | DODECYL ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1951 | DOLICHOS LABLAB | A, H | |
| 1952 | DOLOMITE | A, E, H | |
| 1953 | DRACAENA DRACO | A, H | |
| 1954 | DRIED BUTTERMILK | E | |
| 1955 | DRIED CALCIUM SULFATE | A, E, H | |
| 1956 | DRIED MAGNESIUM SULFATE | A, E, H | When used internally, the maximum recommended daily dose must be no more than 1.5g. Magnesium is a mandatory component of dried magnesium sulfate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or |

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| | | | <p>related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p> |
| 1957 | DRIMIA INDICA | A, H | |
| 1958 | DRIMIA MARITIMA | A, H | |
| 1959 | DROMETRIZOLE TRISILOXANE | A | <p>Only for use as an active ingredient in sunscreens for dermal application.</p> <p>The concentration in a medicine must be no more than 10%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p> |

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| 1960 | DROSERANGLICA | A, H | |
| 1961 | DROSERABURMANNI | A, H | |
| 1962 | DROSERAINTERMEDIA | A, H | |
| 1963 | DROSERARAMENTACIA | A, H | |
| 1964 | DROSERAROTUNDIFOLIA | A, E, H | |
| 1965 | DROSERAROTUNDIFOLIAMIS | A, H | |
| 1966 | DRYNARIAFORTUNEI | A, H | |
| 1967 | DRYOBALANOPSAROMATICA | A, H | |
| 1968 | DRYOPTERISFILIX-MAS | H | Only for use as an active homoeopathic ingredient. |
| 1969 | DULACIAINOPIFLORA | A, H | |
| 1970 | DUNALIELLASALINA | A, E, H | |
| 1971 | DURVILLAEAANTARCTICA EXTRACT | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%. |
| 1972 | DWARFPINE-NEEDLE OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 1973 | DYSPHANIAAMBROSIoidES | A, H | Volatile oil components (of Dysphania ambrosioides) are mandatory components of Dysphania ambrosioides. |
| 1974 | ECAMSULE | A | Only for use as an active ingredient in sunscreens for dermal application. The concentration in the medicine must be no more than 10%. |

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| | | | When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 1975 | ECHINACEA ANGUSTIFOLIA | A, E, H | |
| 1976 | ECHINACEA PALLIDA | A, E, H | |
| 1977 | ECHINACEA PURPUREA | A, E, H | |
| 1978 | ECHINOPA SPINOSISSIMUS | A, H | |
| 1979 | ECLIPTA PROSTRATA | A, H | |
| 1980 | ECTOINE | E | Only for use as an excipient ingredient in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. |
| 1981 | EDETATE SODIUM | E | Only for use in topical medicines for dermal application and nasal medicines. The concentration in the medicine must be no more than 0.2%. |
| 1982 | EDETIC ACID | E | The concentration in the medicine must be no more than 0.25%. |
| 1983 | EGG LECITHIN | A, E | |
| 1984 | EGGSHELL MEMBRANE HYDROLYSATE | A | |
| 1985 | EGGSHELL MEMBRANE POWDER | A | |
| 1986 | ELAEAGNUS ANGUSTIFOLIA | A, H | |
| 1987 | ELAEIS GUINEENSIS | A, E, H | |
| 1988 | ELASTIN | E | Only for use in topical medicines |

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| | | | | for dermal application. |
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| 1989 | ELDER FLOWER ABSOLUTE | E | | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 1990 | ELDER FLOWER BLACK DRY | A, E, H | | |
| 1991 | ELDER FLOWER BLACK POWDER | A, H | | |
| 1992 | ELECAMPANE RHIZOME DRY | A, H | | |
| 1993 | ELECAMPANE RHIZOME POWDER | A, H | | |
| 1994 | ELEMI OIL | E | | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1995 | ELEMI RESINOID | E | | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1996 | ELEMOL | E | | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 1997 | ELEOCHARIS DULCIS | A, H | | |
| 1998 | ELETTARIA CARDAMOMUM | A, E, H | | |

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| 1999 | ELEUTHEROCOCCUS NODIFLORUS | A, H | |
| 2000 | ELEUTHEROCOCCUS ROOT DRY | A, H | |
| 2001 | ELEUTHEROCOCCUS ROOT POWDER | A, H | |
| 2002 | ELEUTHEROCOCCUS SENTICOSUS | A, H | |
| 2003 | ELSHOLTZIA SPLENDENS | A, H | |
| 2004 | ELYMUS REPENS | A, E, H | |
| 2005 | EMU OIL | A, E | Emu oil ingredients must meet the following two requirements: 1) the manufacturing process is to include steps such as cooking, fat drying or deodorising which ensures the temperature of the oil reaches at least 60 degrees C for a minimum 5 minutes or at least 100 degrees C for a minimum of 1 minute, and 2) the sponsor is to hold a veterinary certificate indicating that the emus from which the raw material was extracted were healthy and fit for human consumption. |
| 2006 | EMULSIFYING WAX | E | |
| 2007 | ENOXOLONE | E | Only for use in topical medicines for dermal application. |
| 2008 | ENZYME MODIFIED CREAM | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2009 | EPA-RICH NANNOCHLOROPSIS OCULATA OIL | A, E | Only to be used in a medicine where Lipa Pharmaceuticals Ltd (Client ID 23299), who applied to have the ingredient included in |

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| | | | <p>this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 15 August 2024.</p> <p>The route of administration for medicines that contain EPA-rich <i>Nannochloropsis oculata</i> oil must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 2000 mg of EPA-rich <i>Nannochloropsis oculata</i> oil.</p> <p>The following warning statements (or words to the same effect) must be included on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'. |
| 2010 | EPHEDRA DISTACHYA | A, H | <p>Ephedrine and Pseudoephedrine (of <i>Ephedra distachya</i>) are mandatory components of <i>Ephedra distachya</i> and must be declared in the application.</p> <p>The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p> |
| 2011 | EPHEDRA SINICA | A, H | <p>Ephedrine and Pseudoephedrine (of <i>Ephedra sinica</i>) are mandatory components of <i>Ephedra sinica</i>.</p> <p>The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p> |
| 2012 | EPIGAEA REPENS | A, H | |

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| 2013 | EPILOBIUM ANGUSTIFOLIUM | E | <p>Only for use in topical sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The extract must be processed from the flower, leaf and stem (herb top flowering) of the plant.</p> <p>The extracts used must be: 1:20 in 100% water or 1:2 in 100% water.</p> <p>The concentrations of Epilobium angustifolium must be no more than 0.75% for a 1:2 extract in 100% water, and 5% for a 1:20 extract in 100% water.</p> |
| 2014 | EPILOBIUM PALUSTRE | A, H | |
| 2015 | EPILOBIUM PARVIFLORUM | A, H | |
| 2016 | EPIMEDIUM BREVICORNU | A, H | |
| 2017 | EPIMEDIUM GRANDIFLORUM | A, H | |
| 2018 | EPIMEDIUM SAGITTATUM | A, H | |
| 2019 | EQUISETUM ARVENSE | A, E, H | |
| 2020 | EQUISETUM HIEMALE | A, H | |
| 2021 | ERGOCALCIFEROL | A, E | <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> |
| 2022 | ERGOTHIONEINE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.0005%.</p> |
| 2023 | ERIGERON BREVISCAPUS | A, H | |
| 2024 | ERIOBOTRYA JAPONICA | A, H | <p>Amygdalin and hydrocyanic acid are mandatory components.</p> <p>The concentration of amygdalin in the medicine must be 0%.</p> <p>The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1</p> |

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| | | | microgram/L or 0.000001%. |
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| 2025 | ERIOCAULON BUERGERIANUM | A, H | |
| 2026 | ERIODICTYON CRASSIFOLIUM | A, H | |
| 2027 | ERIODICTYON GLUTINOSUM | A, H | |
| 2028 | ERODIUM CICUTARIUM | A, H | |
| 2029 | ERUCA SATIVA | A, H | |
| 2030 | ERYTHORBIC ACID | E | |
| 2031 | ERYTHRITOL | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%. |
| 2032 | ERYTHROSINE | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 2033 | ERYTHROSINE ALUMINIUM LAKE | E | Permitted for use only as a colour in medicines limited to topical and oral routes of administration. |
| 2034 | ERYTHRULOSE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes'. |
| 2035 | ESCHSCHOLZIA CALIFORNICA | A, H | |
| 2036 | ESTRONE | H | Only for use as an active homoeopathic ingredient. The total concentration of estrone in the medicine must not be more than 100 micrograms/kg or 100 micrograms/L or 0.00001%. |

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| 2037 | ETHANOL | 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. |
| 2038 | ETHANOL ABSOLUTE | A, E | When ethanol absolute is 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. |
| 2039 | ETHER | E | The concentration of ether in the medicine must be no more than 10%. |
| 2040 | ETHOHEXADIOL | E | Only for use in topical medicines for dermal application. The total concentration of ethohexadiol in the medicine must not be more than 5%. |
| 2041 | ETHOXYLATED HYDROGENATED CASTOR OIL | E | |
| 2042 | ETHOXYLATED NONYLPHENOL | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2043 | ETHOXYMETHOXY CYCLODODECANE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a |

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| | | | <p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2044 | ETHYL (2,4-DIMETHYL-[1,3]DIOXOLAN-2-YL) ACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2045 | ETHYL (3AR,4S,7R,7AR)-REL-OCTAHYDRO-4,7-METHANO[3AH]INDENE-3A-CARBOXYLATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2046 | ETHYL 2,3,6,6-TETRAMETHYL-2-CYCLOHEXENECARBOXYLATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2047 | ETHYL 2,6,6,TRIMETHYL-1,3-CYCLOHEXADIENE-1-CARBOXYLATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2048 | ETHYL 2-BUTENOATE | E | <p>Permitted for use only in combination with other permitted</p> |

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| | | | <p>ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 2049 | ETHYL 2-ETHYL-6,6-DIMETHYL-2-CYCLOHEXENECARBOXYLATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2050 | ETHYL 2-HEXYL ACETOACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2051 | ETHYL 2-METHYLBUTYRATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2052 | ETHYL 2-METHYLPENTANOATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a</p> |

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| | | | | medicine must be no more 1%. |
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| 2053 | ETHYL 3-HEXENOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. | |
| 2054 | ETHYL 3-HYDROXYBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. | |
| 2055 | ETHYL 3-HYDROXYHEXANOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. | |
| 2056 | ETHYL 3-MERCAPTOPROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. | |
| 2057 | ETHYL 3-METHYLTHIOPROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. | |
| 2058 | ETHYL 4,7-OCTADIENOATE | E | Permitted for use only in | |

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| | | | <p>combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 2059 | ETHYL ACETATE | E | <p>The residual solvent limit for ethyl acetate is 50 mg per recommended daily dose.</p> <p>The concentration in the medicine must be no more than 0.5%.</p> |
| 2060 | ETHYL ACETOACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2061 | ETHYL ACRYLATE | E | |
| 2062 | ETHYL AMYL KETONE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2063 | ETHYL ANTHRANILATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p> |

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| | | | 5%. |
| 2064 | ETHYL BENZOATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2065 | ETHYL BENZOYL ACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2066 | ETHYL BUTYLACETYLAMINOPROPIONATE | E | <p>Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 7.5%.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (EYE2) 'May be irritant to the eyes (or words to that effect)'.</p> |
| 2067 | ETHYL BUTYRATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |

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| 2068 | ETHYL CAPRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2069 | ETHYL CAPROATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2070 | ETHYL CAPRYLATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2071 | ETHYL CINNAMATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2072 | ETHYL CROTONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. |

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| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2073 | ETHYL ENANTATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2074 | ETHYL FORMATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 2075 | ETHYL HYDROXYBENZOATE | E | |
| 2076 | ETHYL ISOBUTYRATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2077 | ETHYL ISOVALERATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> |

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| | | | <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2078 | ETHYL LACTATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2079 | ETHYL LAURATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2080 | ETHYL LEVULATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> |
| 2081 | ETHYL LEVULINATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total</p> |

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| | | | flavour concentration in a medicine must be no more than 5%. |
| 2082 | ETHYL LINALOOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2083 | ETHYL LINALYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2084 | ETHYL LINOLEATE | E | Only for use in topical medicines for dermal application. |
| 2085 | ETHYL LINOLENATE | E | Only for use in topical medicines for dermal application. |
| 2086 | ETHYL MACADAMIATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. |
| 2087 | ETHYL MALTOL | E | |
| 2088 | ETHYL MENTHANE CARBOXAMIDE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a |

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| | | | medicine must be no more than 5%. |
| 2089 | ETHYL METHACRYLATE | E | <p>Only for use in topical medicines for dermal application.</p> <p>Only permitted in medicines containing 1% or less of ethyl methacrylate as residual monomer in a polymer.</p> |
| 2090 | ETHYL METHYLPHENYLGLYCIDATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2091 | ETHYL METICONE | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p> |
| 2092 | ETHYL MYRISTATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2093 | ETHYL OLEATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a</p> |

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| | | | <p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2094 | ETHYL ORTHO-METHOXYBENZYL ETHER | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2095 | ETHYL OXYHYDRATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2096 | ETHYL PALMITATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2097 | ETHYL PARA-ANISATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> |

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| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2098 | ETHYL PELARGONATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2099 | ETHYL PHENYLACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2100 | ETHYL PHENYLGLYCIDATE | E | <p>Ethyl phenylglycidate must only be used in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The concentration of ethyl phenylglycidate in a medicine must not be more than 0.0000024% w/w (equivalent to 24 parts per billion).</p> |
| 2101 | ETHYL PROPIONATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. |

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| | | | <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2102 | ETHYL PYRUVATE | E | <p>Ethyl pyruvate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of the flavour proprietary excipient formulation containing ethyl pyruvate must not be more than 5% of the total medicine.</p> |
| 2103 | ETHYL RICINOLEATE | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |
| 2104 | ETHYL SALICYLATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p> |
| 2105 | ETHYL SEBACATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a</p> |

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| | | | medicine must be no more than 5%. |
| 2106 | ETHYL STEARATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2107 | ETHYL SUCCINATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2108 | ETHYL TARTRATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2109 | ETHYL TRANS-2, CIS-4-DECADIENOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2110 | ETHYL TRANS-2-HEXENOATE | E | Ethyl trans-2-hexenoate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing ethyl trans-2-hexenoate |

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| | | | must not be more than 5% of the total medicine. |
| 2111 | ETHYL TRANS-3-HEXENOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2112 | ETHYL UNDECYLENATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2113 | ETHYL VALERATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2114 | ETHYL VANILLIN | E | |
| 2115 | ETHYL-2-METHYL-1,3-DIOXOLANE-2-ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2116 | ETHYL-2-METHYL-4-PENTENOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than |

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| | | | 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 2117 | ETHYL-2-METHYLPENTENOATE | E | Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 2118 | ETHYLBISIMINOMETHYL GUAIACOL MANGANESE CHLORIDE | E | Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.002%. |
| 2119 | ETHYLCELLULOSE | E | |
| 2120 | ETHYLENE BRASSYLATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 2121 | ETHYLENE GLYCOL | E | The residual solvent limit for ethylene glycol is 6.2 mg per recommended daily dose. The concentration in the medicine must be no more than 0.062%. |
| 2122 | ETHYLENE GLYCOL MONOPALMITOSTEARATE | E | Only for use in topical medicines for dermal application. |
| 2123 | ETHYLENE/ACRYLIC ACID COPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%. |

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| 2124 | ETHYLENE/VINYL ACETATE COPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 16%. |
| 2125 | ETHYLENEDIAMINE | E | Only for use in topical medicines for dermal application. |
| 2126 | ETHYLENEDIAMINE/HYDROGE NATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. |
| 2127 | ETHYLENEDIAMINE/STEARYL DIMER DILINOLEATE COPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 6%. |
| 2128 | ETHYLHEXYL BENZOATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.5%. |
| 2129 | ETHYLHEXYL METHOXYCRYLENE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. |
| 2130 | ETHYLHEXYL TRIAZONE | A | Only for use as an active ingredient in sunscreens for |

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| | | | <p>dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 5%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| 2131 | ETHYLHEXYLGLYCERIN | E | <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p> |
| 2132 | ETIDRONIC ACID | E | <p>Only for use in topical medicines for dermal application only.</p> <p>The concentration in the medicine must be no more than 1%.</p> |
| 2133 | EUCALYPTUS DIVES | A, E, H | <p>Cineole is a mandatory component of <i>Eucalyptus dives</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none"> a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: |

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| | | | <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p> |
| 2134 | EUCALYPTUS FRUTICETORUM | A, E, H | <p>Cineole is a mandatory component of Eucalyptus fruticetorum.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p> |
| 2135 | EUCALYPTUS GLOBULUS | A, E, H | <p>Cineole is a mandatory component of Eucalyptus globulus.</p> |

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| | | | <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p> |
| 2136 | EUCALYPTUS MACRORHYNCHA | A, E, H | <p>Cineole is a mandatory component of Eucalyptus macrorhyncha.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> |

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| | | | In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure. |
| 2137 | EUCALYPTUS OIL | A, E, H | <p>Cineole is a mandatory component of Eucalyptus oil.</p> <p>When the plant preparation is oil and the total concentration of the oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the plant preparation is oil and the total concentration of the oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’ <p>When the concentration of the oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’ |

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| 2138 | EUCALYPTUS RADIATA | A, E, H | <p>Cineole is a mandatory component of <i>Eucalyptus radiata</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p> |
| 2139 | EUCALYPTUS ROSTRATA | A, E, H | <p>Cineole is a mandatory component of <i>Eucalyptus rostrata</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect);</p> |

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| | | | and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure. |
| 2140 | EUCALYPTUS TERETICORNIS | A, E, H | Cineole is a mandatory component of Eucalyptus tereticornis. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure. |
| 2141 | EUCOMMIA ULMOIDES | A, H | |
| 2142 | EUGENOL | E | When for oral ingestion, eugenol must not comprise more than 0.06% of the formulation. |

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When used in topical medicines for dermal application, the following apply:

a) When the concentration of Eugenol in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.

b) When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label:

- (CHILD) ‘Keep out of reach of children’ (or words to that effect)

- (NTAKEN) ‘Not to be taken’

c) When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15mL, a restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label:

- (CHILD) ‘Keep out of reach of children’ (or words to that effect)

- (NTAKEN) ‘Not to be taken’

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| 2143 | EUGENYL ACETATE | E | <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a</p> |
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| | | | medicine must be no more 1%. |
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| 2144 | EUGLENA GRACILIS WHOLE CELL DRY | A | <p>Only to be used in a medicine where Kemin Foods LC (Client ID 29988), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 March 2024.</p> <p>The route of administration for medicines that contain <i>Euglena gracilis</i> whole cell dry must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(a) 100 mg of <i>Euglena gracilis</i> whole cell dry for children aged between 1 and 3 years (inclusive);</p> <p>(b) 150 mg of <i>Euglena gracilis</i> whole cell dry for children aged between 4 and 8 years (inclusive);</p> <p>(c) 225 mg of <i>Euglena gracilis</i> whole cell dry for individuals aged between 9 and 18 years (inclusive); and</p> <p>(d) 375 mg of <i>Euglena gracilis</i> whole cell dry for adults aged 19 years or older.</p> <p>The following warning statement (or words to the same effect) must be included on the medicine label:</p> <p>- (BABY2) 'Not suitable for infants under the age of twelve months'.</p> |
| 2145 | EUONYMUS ATROPURPUREUS | A, H | |
| 2146 | EUONYMUS EUROPAEUS | A, H | The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry |

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| | | | herbal material. |
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| 2147 | EUPATORIUM FORTUNEI | A, H | |
| 2148 | EUPATORIUM JAPONICUM | A, H | |
| 2149 | EUPATORIUM PERFOLIATUM | A, H | |
| 2150 | EUPATORIUM PURPUREUM | A, H | |
| 2151 | EUPHAUSIA SUPERBA OIL | A | Only for use in oral medicines. |
| 2152 | EUPHORBIA CYPARISSIAS | A, H | |
| 2153 | EUPHORBIA DRY | A, H | |
| 2154 | EUPHORBIA HETERODOXA | A, H | |
| 2155 | EUPHORBIA HIRTA | A, H | |
| 2156 | EUPHORBIA LATHYRIS | A | Levodopa is a mandatory component of Euphorbia lathyris. The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |
| 2157 | EUPHORBIA PEKINENSIS | A, H | |
| 2158 | EUPHORBIA PEPLUS | H | Only for use as an active homoeopathic ingredient. |
| 2159 | EUPHORBIA POWDER | A, H | |
| 2160 | EUPHORBIA RESINIFERA | A, H | |
| 2161 | EUPHORBIA SIEBOLDIANA | A, H | |
| 2162 | EUPHRASIA OFFICINALIS | A, H | |
| 2163 | EUROPEAN GARDEN SPIDER | H | Only for use as an active homoeopathic ingredient. |
| 2164 | EUROPEAN HORNET | H | Only for use as an active homoeopathic ingredient. |
| 2165 | EURYALE FEROX | A, H | |
| 2166 | EUTERPE OLERACEA | A, E | The plant part must be derived from the fruit. When used as an excipient: - permitted for use only in combination with other permitted ingredients as a flavour |

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| | | | <p>proprietary excipient formulation;</p> <ul style="list-style-type: none"> - the total flavour proprietary excipient formulation in a medicine must not be more than 5%; and - the following warning statement is required on the medicine label: <ul style="list-style-type: none"> - (ACAI) ‘Contains acai’. |
| 2167 | EVENING PRIMROSE OIL | A, E, H | |
| 2168 | EVERNIA PRUNASTRI EXTRACT | E | <p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> |

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