Volume 6

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

Note: See sections 5 and 6.

**Permissible ingredients and requirements**

| Column 1 | Column 2 | Column 3 | Column 4 |
|---|---|---|---|
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| 5077 | UBIDECARENONE | A, E | When used as an excipient, the route of administration must be topical and the concentration in the medicine must not be more than 0.05%.<br>Not to be included in medicines intended for use in the eye.<br>When for internal use, the maximum recommended daily dose must not provide more than 300 milligrams of ubidecarenone.<br>When for internal use in combination with Ubiquinol-10, the maximum recommended daily dose must not provide more than 300 milligrams of ubiquinol-10 and ubidecarenone combined.<br>When for internal use, the following warning statement is required on the medicine label:<br>- (WARF) 'Do not take while on warfarin therapy without medical advice'. |
| 5078 | UBIQUINOL-10 | A, E | When used as an excipient, the route of administration must be topical and the concentration in the medicine must be no more than 0.05%.<br>Not to be included in medicines intended for use in the eye.<br>When for internal use, the maximum recommended daily dose must provide no more |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | than 300 milligrams of ubiquinol-10.<br>When used in combination with ubidecarenone, the maximum recommended daily dose must provide no more than 300 mg of ubiquinol-10 and ubidecarenone combined.<br>The medicine requires the following warning statement on the medicine label:<br>- (WARF) 'Do not take while on warfarin therapy without medical advice.' |
| 5079 | ULEX EUROPAEUS | A, H | |
| 5080 | ULMUS AMERICANA | A, H | |
| 5081 | ULMUS CAMPESTRIS | A, H | |
| 5082 | ULMUS GLABRA | A, H | |
| 5083 | ULMUS MINOR | A, H | |
| 5084 | ULMUS PARVIFOLIA | A, H | |
| 5085 | ULMUS PUMILA | A, H | |
| 5086 | ULMUS RUBRA | A, H | |
| 5087 | ULTRALIDE | E | Permitted for use only in combination with other permitted ingredients as a fragrance.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5088 | ULTRAMARINE BLUE | E | Permitted for use only as a colour for topical use. |
| 5089 | ULVA LACTUCA | A, H | Iodine is a mandatory component of Ulva lactuca.<br>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. |

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | The concentration in the medicine must be no more than 0.1%. |
| 5090 | UMBELLULARIA CALIFORNICA | A, H | |
| 5091 | UNCARIA GAMBIR | A, H | |
| 5092 | UNCARIA RHYNCOPHYLLA | A, H | |
| 5093 | UNCARIA SINENSIS | A, H | |
| 5094 | UNCARIA TOMENTOSA | A, H | |
| 5095 | UNDARIA PINNATIFIDA | A, H | Whole dried Undaria pinnatifida must not contain the holdfast.<br>Only for use in oral medicines. |
| 5096 | UNDECANAL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 5097 | UNDECANOIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used as a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5098 | UNDECENOIC ACID | E | |
| 5099 | UNDECYL ALCOHOL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 5100 | UNDECYLCRYLENE DIMETICONE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 10%. |
| 5101 | UNDECYLENAMIDE DEA | E | |
| 5102 | UNDECYLENOYL PEG-5 PARABEN | E | Only for use in topical medicines for dermal application. |
| 5103 | URANIUM NITRATE | H | Only for use as an active homoeopathic ingredient. |
| 5104 | UREA | A, E, H | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 10% (w/w). |
| 5105 | URTICA DIOICA | A, E, H | |
| 5106 | URTICA URENS | A, H | |
| 5107 | USNEA BARBATA | A, H | |
| 5108 | UVA URSI LEAF DRY | A, H | |
| 5109 | UVA URSI LEAF POWDER | A, E, H | |
| 5110 | VA/BUTYL MALEATE/ISOBORNYL ACRYLATE COPOLYMER | E | Vinyl acetate is a mandatory component of VA/butyl maleate/isobornyl acrylate copolymer.<br>The concentration of vinyl acetate in the medicine must be no more than 0.01% or 100 |

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

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | ppm.<br>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 5%. |
| 5111 | VACCARIA SEGATALIS | A, H | |
| 5112 | VACCINIUM BRACTEATUM | A, H | |
| 5113 | VACCINIUM CORYMBOSUM | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5114 | VACCINIUM MACROCARPON | A, E, H | |
| 5115 | VACCINIUM MYRTILLOIDES | A, H | |
| 5116 | VACCINIUM MYRTILLUS | A, E, H | |
| 5117 | VACCINIUM OXYCOCCUS | A, H | |
| 5118 | VACCINIUM VITIS-IDAEA | A, H | Beta-arbutin is a mandatory component of Vaccinium vitis-idaea.<br>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.<br>When for dermal application exclusively to the face:<br>a) the concentration of beta-arbutin in the medicine must not be more than 7%;<br>b) hydroquinone is a mandatory component; and<br>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | mg/L or 0.001%.<br>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |
| 5119 | VALENCENE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5120 | VALERALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5121 | VALERIAN DRY | A, H | |
| 5122 | VALERIAN OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5123 | VALERIAN POWDER | A, H | |
| 5124 | VALERIANA EDULIS | A, H | |
| 5125 | VALERIANA OFFICINALIS | A, H | |
| 5126 | VALERIANA SORBIFOLIA | A, H | |
| 5127 | VALERIC ACID | E | Permitted for use only in combination with other permitted ingredients as a |

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5128 | VALINE | A, E | |
| 5129 | VANADIUM | H | |
| 5130 | VANILLA | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 5131 | VANILLA DRY | A, E, H | |
| 5132 | VANILLA EXTRACT | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5133 | VANILLA OLEORESIN | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5134 | VANILLA PLANIFOLIA | A, E, H | |
| 5135 | VANILLA POWDER | A, E, H | |
| 5136 | VANILLA TAHITENSIS | A, H | |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| 5137 | VANILLIC ACID | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5138 | VANILLIN | E | |
| 5139 | VANILLIN ISOBUTYRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 5140 | VANILLYL ALCOHOL | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5141 | VAT RED 1 | E | Permitted for use only as a colour for topical use. |
| 5142 | VAT RED 1 ALUMINIUM LAKE | E | Permitted for use only as a colour for topical use. |
| 5143 | VAT RED 5 | E | Permitted for use only as a colour for topical use. |
| 5144 | VEGETABLE OIL | E | |
| 5145 | VEGETABLE OIL | A | Only for use in oral medicines. |

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | PHYTOSTEROL ESTERS | | The medicine requires the following warning statement on the medicine label:<br>- (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).' |
| 5146 | VEIN | H | Only for use as an active homoeopathic ingredient. |
| 5147 | VERATRALDEHYDE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 5148 | VERATROL | E | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.<br>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 5149 | VERATRUM ALBUM | A, H | Solanidine is a mandatory component of Veratrum album.<br>The concentration of equivalent dry Veratrum album in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%. |
| 5150 | VERBASCUM DENSIFLORUM | A, H | |
| 5151 | VERBASCUM THAPSUS | A, H | |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| 5152 | VERBENA OFFICINALIS | A, H | |
| 5153 | VERBENA OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5154 | VERONICA CHAMAEDRYS | A, H | |
| 5155 | VERONICA OFFICINALIS | A, H | |
| 5156 | VERONICASTRUM VIRGINICUM | A, E, H | |
| 5157 | VERTONAL | E | Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.<br>When included in a medicine for use on the lips the concentration of vertonal must be no more than 0.2%.<br>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%. |
| 5158 | VETIVER OIL | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 5159 | VETIVERYL ACETATE | E | Permitted for use only in combination with other permitted ingredients as a fragrance. |

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. |
| 5160 | VIBURNUM OPULUS | A, E, H | |
| 5161 | VIBURNUM PRUNIFOLIUM | A, E, H | |
| 5162 | VICIA FABA | A, H | Levodopa is a mandatory component of Vicia faba.<br>The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. |
| 5163 | VIGNA ANGULARIS VAR. ANGULARIS | A, H | |
| 5164 | VIGNA RADIATA | A, H | |
| 5165 | VIGNA UMBELLATA | A, H | |
| 5166 | VINCA MAJOR | A, H | Vincamine is a mandatory component of Vinca major.<br>The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%. |
| 5167 | VINCA MINOR | A, H | Vincamine and vincristine are mandatory components of Vinca minor.<br>The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.<br>The concentration of Vincristine in the medicine must be no more than 10mg/kg or 10mg/L or 0.001% |
| 5168 | VINCETOXICUM OFFICINALE | A, H | |
| 5169 | VINEGAR | E | Permitted for use only in combination with other permitted ingredients as a flavour. |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5170 | VIOLA ODORATA | A, E, H | |
| 5171 | VIOLA TRICOLOR | A, H | |
| 5172 | VIOLA YEDOENSIS | A, H | |
| 5173 | VIOLET LEAF ABSOLUTE | E | Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.<br>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. |
| 5174 | VIPER | H | Only for use as an active homoeopathic ingredient. |
| 5175 | VISCUM ALBUM | A, E, H | |
| 5176 | VISCUM COLORATUM | A, H | |
| 5177 | VISCUM FLAVESCENS | A, H | |
| 5178 | VITELLARIA PARADOXA | A, E, H | |
| 5179 | VITEX AGNUS-CASTUS | A, E, H | When the ingredient is in a medicine that is for internal use and is listed in the Register on or after 2 March 2020, or that is released for supply after 2 March 2021, the following warning statement is required on the label:<br>- (VAC) 'Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect). |

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

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| 5180 | VITEX NEGUNDO | A, H | |
| 5181 | VITEX ROTUNDIFOLIA | A, H | |
| 5182 | VITEX TRIFOLIA | A, H | |
| 5183 | VITIS VINIFERA | A, E, H | |
| 5184 | VITREOSCILLA CONCENTRATE | E | Only for use in topical medicines for dermal application.<br>The concentration in the medicine must be no more than 0.1%. |
| 5185 | VP/ACRYLATES/LAURYL METHACRYLATE COPOLYMER | E | Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 2.00%. |
| 5186 | WAHLENBERGIA GRACILIS | A, H | |
| 5187 | WALNUT | E | |
| 5188 | WALNUT OIL | E | |
| 5189 | WATER MELON | E | |
| 5190 | WHEAT | E | Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal. |
| 5191 | WHEAT BRAN | E | Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal. |
| 5192 | WHEAT DEXTRIN | A, E | Gluten is a mandatory component of wheat dextrin.<br>Only for use when the dosage form is capsule, tablet or pill. |
| 5193 | WHEAT GERM | E | Gluten is a mandatory |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | component of Wheat germ when the route of administration is other than topical and mucosal. |
| 5194 | WHEAT GERM GLYCERIDES | E | Gluten is a mandatory component of wheat germ glycerides when the route of administration is other than topical and mucosal. |
| 5195 | WHEAT LEAF | E | |
| 5196 | WHEAT SPROUT | E | Gluten is a mandatory component of Wheat sprout when the route of administration is other than topical and mucosal. |
| 5197 | WHEAT STARCH | E | When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch. |
| 5198 | WHEATGERM OIL | A, E, H | |
| 5199 | WHEY POWDER | E | Lactose is a mandatory component of Whey powder when the route of administration is oral. |
| 5200 | WHEY PROTEIN | E | Lactose is a mandatory component of Whey protein when the route of administration is oral. |
| 5201 | WHEY PROTEIN CONCENTRATE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |

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

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| 5202 | WHITE BEESWAX | E | |
| 5203 | WHITE HOREHOUND HERB DRY | A, H | |
| 5204 | WHITE HOREHOUND HERB POWDER | A, H | |
| 5205 | WHITE SOFT PARAFFIN | 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. |
| 5206 | WHOLE DRY MILK | E | |
| 5207 | WIKSTROEMIA VIRIDIFLORA | A, H | |
| 5208 | WILD CARROT HERB DRY | A, E, H | |
| 5209 | WILD CARROT HERB POWDER | A, H | |
| 5210 | WILD CHERRY BARK DRY | A, H | |
| 5211 | WILD CHERRY BARK POWDER | A, H | |
| 5212 | WILD LETTUCE LEAF DRY | A, H | |
| 5213 | WILD LETTUCE LEAF POWDER | A, H | |
| 5214 | WINTERGREEN OIL | A, E, H | Methyl salicylate is a mandatory component of wintergreen oil.<br>Not to be included in medicines for use in the eye or on damaged skin.<br>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.<br>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.<br>When the concentration of |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | 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:<br>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;<br>- direct suction through the delivery device results in delivery of no more than one dosage unit; and<br>- actuation of the spray device is ergonomically difficult for young children to accomplish.<br>The following warning statement is required on the medicine label:<br>- (METSAL) 'Contains methyl salicylate' (or words to that effect).<br>When for use in topical medicines for dermal application:<br>i) the concentration of methyl salicylate in the medicine must not be more than 25%;<br>ii) the following warning statements are required on the medicine label:<br>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);<br>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';<br>- (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect);<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words |

Volume 6

**Permissible ingredients and requirements**

| Column 1 | Column 2 | Column 3 | Column 4 |
|---|---|---|---|
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | to that effect);<br>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:<br>- (IRRIT) 'If irritation develops, discontinue use'. |
| 5215 | WITHANIA SOMNIFERA | A, E, H | The requirements specified in paragraph (a) below apply in relation to a medicine that contains the ingredient that:<br>- is listed in the Register on or after 2 March 2020; or<br>- is released for supply after 2 March 2021.<br>(a) The medicine requires the following warning statement on the label:<br>- (WITHANIA) 'If you are pregnant, or considering becoming pregnant, do not take without consulting a health professional' (or words to that effect)<br>unless:<br>(i) the plant part is root;<br>(ii) the plant preparation is an extract;<br>(iii) the extraction solvents are only water, ethanol or methanol; and<br>(iv) the maximum recommended daily dose of the medicine contains no more than the equivalent quantity of 12 g dry root. |
| 5216 | WOLFIPORIA COCOS | A, E, H | |
| 5217 | WOOL ALCOHOLS | E | Only for use in topical |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | medicines for dermal application. |
| 5218 | WOOL FAT | 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. |
| 5219 | XANTHAN GUM | E | |
| 5220 | XANTHIUM SIBIRICUM | A, H | |
| 5221 | XANTHIUM STRUMARIUM | A, H | |
| 5222 | XANTHOMONA CAMPESTRIS | A, H | |
| 5223 | XEROPHYLLUM ASPHODELOIDES | A, H | |
| 5224 | XYLENE | E | The residual solvent limit for xylene is 21.7 mg per maximum recommended daily dose.<br>The concentration in the medicine must be no more than 0.217%. |
| 5225 | XYLITOL | E | |
| 5226 | XYLOSE | E | |
| 5227 | YAM | E | |
| 5228 | YARROW HERB DRY | A, H | |
| 5229 | YARROW HERB POWDER | A, H | |
| 5230 | YEAST AUTOLYSATE | E | |
| 5231 | YEAST DRIED | A, E, H | |
| 5232 | YELLOW 2G | E | Permitted for use only as a colour for topical use. |
| 5233 | YELLOW BEESWAX | E | |
| 5234 | YELLOW MERCURIC OXIDE | H | Only for use as an active homoeopathic ingredient. |

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

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| 5235 | YELLOW SOFT PARAFFIN | A, E | Only for use in topical medicines for dermal application.<br>When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. |
| 5236 | YLANG YLANG OIL | A, E, H | |
| 5237 | YUCCA BACCATA | A, H | |
| 5238 | YUCCA ELATA | A, H | |
| 5239 | YUCCA FILAMENTOSA | A, H | |
| 5240 | YUCCA GLORIOSA | A, H | |
| 5241 | ZANTHOXYLUM AMERICANUM | A, H | |
| 5242 | ZANTHOXYLUM BUNGEANUM | A, E, H | |
| 5243 | ZANTHOXYLUM CLAVA-HERCULIS | A, H | |
| 5244 | ZANTHOXYLUM NITIDUM | A, H | |
| 5245 | ZANTHOXYLUM PIPERITUM | A, H | |
| 5246 | ZANTHOXYLUM SIMULANS | A, H | |
| 5247 | ZEA MAYS | A, E, H | |
| 5248 | ZEAXANTHIN | A, E | |
| 5249 | ZEIN | E | |
| 5250 | ZINC | H | Only for use as an active homoeopathic ingredient.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. |
| 5251 | ZINC AMINO ACID CHELATE | A, E, H | When used internally, zinc is a mandatory component of zinc amino acid chelate.<br>The concentration of zinc in zinc amino acid chelate must be no more than 30%.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5252 | ZINC ASCORBATE | A, E, H | When used internally, zinc is a mandatory component of zinc ascorbate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the |

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

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5253 | ZINC ASCORBATE MONOHYDRATE | A, E, H | When used internally, zinc is a mandatory component of zinc ascorbate monohydrate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. |
| 5254 | ZINC CHLORIDE | A, E, H | The concentration of zinc chloride in the medicine must be no more than 5%.<br>When used internally, zinc is a mandatory component of zinc chloride.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5255 | ZINC CITRATE | A, E, H | When used internally, zinc is a mandatory component of zinc citrate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5256 | ZINC CITRATE DIHYDRATE | A, E, H | When used internally, zinc is a mandatory component of zinc citrate dihydrate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. |

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5257 | ZINC CITRATE TRIHYDRATE | A, E, H | When used internally, zinc is a mandatory component of zinc citrate trihydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5258 | ZINC DIASPARTATE | A | When used internally, zinc is a mandatory component of zinc diaspartate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5259 | ZINC GLUCONATE | A, E, H | When used internally, zinc is a mandatory component of zinc gluconate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5260 | ZINC GLYCINATE | A | When used internally, zinc is a mandatory component of Zinc glycinate.<br>When for internal use, the maximum recommended daily dose must be no more than |

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5261 | ZINC GLYCINATE MONOHYDRATE | A | When used internally, zinc is a mandatory component of Zinc glycinate monohydrate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. |
| 5262 | ZINC LACTATE | E | Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye.<br>The concentration of zinc |

| Permissible ingredients and requirements | | | |
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| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | lactate in a medicine intended for topical use should be no more than 2%.<br>The concentration of Zinc lactate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%.<br>Zinc lactate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old.<br>Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label:<br>- (CHILD3) 'Use in children under 12 years is not recommended'. |
| 5263 | ZINC LACTATE DIHYDRATE | E | Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye.<br>The concentration of Zinc lactate dihydrate in a medicine intended for topical use should be no more than 2%.<br>The concentration of Zinc lactate dihydrate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%.<br>Zinc lactate dihydrate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old.<br>Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label:<br>- (CHILD3) 'Use in children |

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | under 12 years is not recommended'. |
| 5264 | ZINC LYSINATE | A | When used internally, zinc is a mandatory component of Zinc lysinate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5265 | ZINC METHIONINE SULFATE | A | For topical use, the concentration of zinc methionine sulfate must be no more than 5%.<br>When used internally, zinc is a mandatory component of zinc methionine sulfate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5266 | ZINC MYRISTATE | E | Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must be no more than 0.1%. |
| 5267 | ZINC OXIDE | A, E, H | When used internally, zinc is a mandatory component of zinc oxide.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR<br>-'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect).<br>When used in primary sunscreen products, the following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear |

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

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | when exposed to the sun' (or words to this effect). |
| 5268 | ZINC PARA-PHENOLSULFONATE | E | The concentration of zinc para-phenolsulfonate in the medicine must not exceed 5%.<br>When used internally, zinc is a mandatory component of zinc para-phenolsulfate.<br>The percentage of zinc from zinc para-phenolsulfonate should be calculated based on the molecular weight of zinc para-phenolsulfonate.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect). |
| 5269 | ZINC STEARATE | E | When used internally, zinc is a mandatory component of zinc stearate.<br>The percentage of zinc from zinc stearate should be calculated based on the molecular weight of zinc stearate. |
| 5270 | ZINC SUCCINATE | A, E, H | When used internally, zinc is a mandatory component of zinc succinate.<br>When for internal use, the maximum recommended daily |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' or<br>- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5271 | ZINC SULFATE | A, E | For topical use, the concentration of zinc sulfate must be no more than 5%.<br>For internal use, zinc is a mandatory component of zinc sulfate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR<br>- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |

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

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| 5272 | ZINC SULFATE HEPTAHYDRATE | A, E | For topical use, the concentration of zinc sulfate must be no more than 5%.<br>For internal use, zinc is a mandatory component of zinc sulfate heptahydrate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR<br>- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5273 | ZINC SULFATE HEXAHYDRATE | A, E, H | For topical use, the concentration of zinc sulfate must be no more than 5%.<br>For internal use, zinc is a mandatory component of zinc sulfate hexahydrate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement |

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR<br>- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5274 | ZINC SULFATE MONOHYDRATE | A, E, H | When the route of administration is topical the concentration of zinc sulfate in the medicine must be no more than 5%.<br>When the medicine is for internal use, zinc is a mandatory component of zinc sulfate monohydrate.<br>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.<br>When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:<br>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR<br>- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' |
| 5275 | ZINC VALERATE | H | Only for use as an active homoeopathic ingredient.<br>For internal use, zinc is a |

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

Volume 6

| Permissible ingredients and requirements | | | |
|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** |
| **Item** | **Ingredient name** | **Purpose** | **Specific requirements** |
| | | | mandatory component of zinc valerate.<br>The percentage of zinc from zinc valerate should be calculated based on the molecular weight of zinc valerate. |
| 5276 | ZINGERONE | E | Permitted for use only in combination with other permitted ingredients as a flavour.<br>If used in a flavour the total flavour concentration in a medicine must be no more than 5%. |
| 5277 | ZINGIBER OFFICINALE | A, E, H | When for oral use AND the extract ratio is equal to or more than 25:1 AND the equivalent dry weight per dosage unit is equal to or more than 2g, the medicine requires the following warning statement on the medicine label:<br>- (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine'. |
| 5278 | ZIZIPHUS JUJUBA | A, H | |
| 5279 | ZIZIPHUS JUJUBA VAR. SPINOSA | A, H | |
| 5280 | ZIZYPHUS SATIVA | A, H | |
| 5281 | ZOSTERA MARINA | A, H | |
| 5282 | ZUCCHINI | E | |

Volume 6

# Schedule 2—Repeals

Note: See section 7.

## *Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2020*

### 1 The whole of the instrument

Repeal the instrument.