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**
5085	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%. Not to be included in medicines intended for use in the eye. When for internal use, the maximum recommended daily dose must not provide more than 300 milligrams of ubidecarenone. 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. When for internal use, the following warning statement is required on the medicine label: - (WARF) 'Do not take while on warfarin therapy without medical advice'.
5086	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%. Not to be included in medicines intended for use in the eye. When for internal use, the maximum recommended daily dose must provide no more

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			than 300 milligrams of ubiquinol-10. When used in combination with ubidecarenone, the maximum recommended daily dose must provide no more than 300 mg of ubiquinol-10 and ubidecarenone combined. The medicine requires the following warning statement on the medicine label: - (WARF) 'Do not take while on warfarin therapy without medical advice.'
5087	ULEX EUROPAEUS	A, H	
5088	ULMUS AMERICANA	A, H	
5089	ULMUS CAMPESTRIS	A, H	
5090	ULMUS GLABRA	A, H	
5091	ULMUS MINOR	A, H	
5092	ULMUS PARVIFOLIA	A, H	
5093	ULMUS PUMILA	A, H	
5094	ULMUS RUBRA	A, H	
5095	ULTRALIDE	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%.
5096	ULTRAMARINE BLUE	E	Permitted for use only as a colour for topical use.
5097	ULVA LACTUCA	A, H	Iodine is a mandatory component of Ulva lactuca. Only for use in 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%.

5098	UMBELLULARIA CALIFORNICA	A, H	
5099	UNCARIA GAMBIR	A, H	
5100	UNCARIA RHYNCOPHYLLA	A, H	
5101	UNCARIA SINENSIS	A, H	
5102	UNCARIA TOMENTOSA	A, H	
5103	UNDARIA PINNATIFIDA	A, H	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
5104	UNDECANAL	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%.
5105	UNDECANOIC ACID	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%.
5106	UNDECENOIC ACID	E	
5107	UNDECYL 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%.
5108	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. The concentration in the medicine must be no more than 10%.
5109	UNDECYLENAMIDE DEA	E	
5110	UNDECYLENOYL PEG-5 PARABEN	E	Only for use in topical medicines for dermal application.
5111	URANIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
5112	UREA	A, E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10% (w/w).
5113	URTICA DIOICA	A, E, H	
5114	URTICA URENS	A, H	
5115	USNEA BARBATA	A, H	
5116	UVA URSI LEAF DRY	A, H	
5117	UVA URSI LEAF POWDER	A, E, H	
5118	VA/BUTYL MALEATE/ISOBORNYL ACRYLATE COPOLYMER	E	Vinyl acetate is a mandatory component of VA/butyl maleate/isobornyl acrylate copolymer. The concentration of vinyl acetate in the medicine must be no more than 0.01% or 100 ppm. Only for use in 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%.
5119	VACCARIA SEGATALIS	A, H	

5120	VACCINIUM BRACTEATUM	A, H	
5121	VACCINIUM CORYMBOSUM	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%.
5122	VACCINIUM MACROCARPON	A, E, H	
5123	VACCINIUM MYRTILLOIDES	A, H	
5124	VACCINIUM MYRTILLUS	A, E, H	
5125	VACCINIUM OXYCOCCUS	A, H	
5126	VACCINIUM VITIS-IDAEA	A, H	Beta-arbutin is a mandatory component of Vaccinium vitis-idaea. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5127	VALENCENE	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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5128	VALERALDEHYDE	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%.
5129	VALERIAN DRY	A, H	
5130	VALERIAN 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%.
5131	VALERIAN POWDER	A, H	
5132	VALERIANA EDULIS	A, H	
5133	VALERIANA OFFICINALIS	A, H	
5134	VALERIANA SORBIFOLIA	A, H	
5135	VALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5136	VALINE	A, E	
5137	VANADIUM	H	
5138	VANILLA	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%.

5139	VANILLA DRY	A, E, H	
5140	VANILLA 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%.
5141	VANILLA OLEORESIN	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%.
5142	VANILLA PLANIFOLIA	A, E, H	
5143	VANILLA POWDER	A, E, H	
5144	VANILLA TAHITENSIS	A, H	
5145	VANILLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5146	VANILLIN	E	
5147	VANILLIN ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5148	VANILLYL ALCOHOL	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%.
5149	VAT RED 1	E	Permitted for use only as a colour for topical use.
5150	VAT RED 1 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
5151	VAT RED 5	E	Permitted for use only as a colour for topical use.
5152	VEGETABLE OIL	E	
5153	VEGETABLE OIL PHYTOSTEROL ESTERS	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'
5154	VEIN	H	Only for use as an active homoeopathic ingredient.
5155	VERATRALDEHYDE	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%.
5156	VERATROL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary

			excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
5157	VERATRUM ALBUM	A, H	Solanidine is a mandatory component of Veratrum album. The concentration of equivalent dry Veratrum album in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
5158	VERBASCUM DENSIFLORUM	A, H	
5159	VERBASCUM THAPSUS	A, H	
5160	VERBENA OFFICINALIS	A, H	
5161	VERBENA 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%.
5162	VERONICA CHAMAEDRYS	A, H	
5163	VERONICA OFFICINALIS	A, H	
5164	VERONICASTRUM VIRGINICUM	A, E, H	
5165	VERTONAL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. When included in a medicine for use on the lips the concentration of vertonal must be no more than 0.2%. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
5166	VETIVER OIL	E	Permitted for use only in combination with other permitted ingredients as 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%.
5167	VETIVERYL 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%.
5168	VIBURNUM OPULUS	A, E, H	
5169	VIBURNUM PRUNIFOLIUM	A, E, H	
5170	VICIA FABA	A, H	Levodopa is a mandatory component of Vicia faba. The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5171	VIGNA ANGULARIS VAR. ANGULARIS	A, H	
5172	VIGNA RADIATA	A, H	
5173	VIGNA UMBELLATA	A, H	
5174	VINCA MAJOR	A, H	Vincamine is a mandatory component of Vinca major. The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
5175	VINCA MINOR	A, H	Vincamine and vincristine are mandatory components of Vinca minor. The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%. The concentration of

			Vincristine in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%
5176	VINCETOXICUM OFFICINALE	A, H	
5177	VINEGAR	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%.
5178	VIOLA ODORATA	A, E, H	
5179	VIOLA TRICOLOR	A, H	
5180	VIOLA YEDOENSIS	A, H	
5181	VIOLET LEAF 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%.
5182	VIPER	H	Only for use as an active homoeopathic ingredient.
5183	VISCUM ALBUM	A, E, H	
5184	VISCUM COLORATUM	A, H	
5185	VISCUM FLAVESCENS	A, H	
5186	VITELLARIA PARADOXA	A, E, H	
5187	VITEX AGNUS-CASTUS	A, E, H	When the ingredient is in a medicine that is for internal use, the following warning statement is required on the label: - (VAC) 'Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use'

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			(or words to that effect).
5188	VITEX NEGUNDO	A, H	
5189	VITEX ROTUNDIFOLIA	A, H	
5190	VITEX TRIFOLIA	A, H	
5191	VITIS VINIFERA	A, E, H	
5192	VITREOSCILLA CONCENTRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
5193	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. The concentration in the medicine must not be more than 2.00%.
5194	WAHLENBERGIA GRACILIS	A, H	
5195	WALNUT	E	
5196	WALNUT OIL	E	
5197	WATER MELON	E	
5198	WHEAT	E	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal.
5199	WHEAT BRAN	E	Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal.
5200	WHEAT DEXTRIN	A, E	Gluten is a mandatory component of wheat dextrin. Only for use when the dosage form is capsule, tablet or pill.
5201	WHEAT GERM	E	Gluten is a mandatory component of Wheat germ when the route of

			administration is other than topical and mucosal.
5202	WHEAT GERM GLYCERIDES	E	Gluten is a mandatory component of wheat germ glycerides when the route of administration is other than topical and mucosal.
5203	WHEAT LEAF	E	
5204	WHEAT SPROUT	E	Gluten is a mandatory component of Wheat sprout when the route of administration is other than topical and mucosal.
5205	WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch.
5206	WHEATGERM OIL	A, E, H	
5207	WHEY POWDER	E	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5208	WHEY PROTEIN	E	Lactose is a mandatory component of Whey protein when the route of administration is oral.
5209	WHEY PROTEIN CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5210	WHITE BEESWAX	E	
5211	WHITE HOREHOUND HERB DRY	A, H	
5212	WHITE HOREHOUND HERB POWDER	A, H	

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5213	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.
5214	WHOLE DRY MILK	E	
5215	WIKSTROEMIA VIRIDIFLORA	A, H	
5216	WILD CARROT HERB DRY	A, E, H	
5217	WILD CARROT HERB POWDER	A, H	
5218	WILD CHERRY BARK DRY	A, H	
5219	WILD CHERRY BARK POWDER	A, H	
5220	WILD LETTUCE LEAF DRY	A, H	
5221	WILD LETTUCE LEAF POWDER	A, H	
5222	WINTERGREEN OIL	A, E, H	Methyl salicylate is a mandatory component of wintergreen oil. 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 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 the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
5223	WITHANIA SOMNIFERA	A, E, H	The medicine requires the following warning statement on the label:

			- (WITHANIA) 'If you are pregnant, or considering becoming pregnant, do not take without consulting a health professional' (or words to that effect) unless: (a) the plant part is root; (b) the plant preparation is an extract; (c) the extraction solvents are only water, ethanol or methanol; and (d) the maximum recommended daily dose of the medicine contains no more than the equivalent quantity of 12 g dry root.
5224	WOLFIPORIA COCOS	A, E, H	
5225	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.
5226	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.
5227	XANTHAN GUM	E	
5228	XANTHIUM SIBIRICUM	A, H	
5229	XANTHIUM STRUMARIUM	A, H	
5230	XANTHOMONA CAMPESTRIS	A, H	
5231	XEROPHYLLUM ASPHODELOIDES	A, H	
5232	XYLENE	E	The residual solvent limit for xylene is 21.7 mg per maximum recommended daily dose. The concentration in the

			medicine must be no more than 0.217%.
5233	XYLITOL	E	
5234	XYLOSE	E	
5235	YAM	E	
5236	YARROW HERB DRY	A, H	
5237	YARROW HERB POWDER	A, H	
5238	YEAST AUTOLYSATE	E	
5239	YEAST DRIED	A, E, H	
5240	YELLOW 2G	E	Permitted for use only as a colour for topical use.
5241	YELLOW BEESWAX	E	
5242	YELLOW MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
5243	YELLOW SOFT PARAFFIN	A, E	Only for use in topical medicines for dermal application. 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.
5244	YLANG YLANG OIL	A, E, H	
5245	YUCCA BACCATA	A, H	
5246	YUCCA ELATA	A, H	
5247	YUCCA FILAMENTOSA	A, H	
5248	YUCCA GLORIOSA	A, H	
5249	Z-BETA-DAMASCONE	E	Z – beta damascone 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 Z –

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			beta damascone must not be more than 5% of the total medicine.
5250	ZANTHOXYLUM AMERICANUM	A, H	
5251	ZANTHOXYLUM BUNGEANUM	A, E, H	
5252	ZANTHOXYLUM CLAVA-HERCULIS	A, H	
5253	ZANTHOXYLUM NITIDUM	A, H	
5254	ZANTHOXYLUM PIPERITUM	A, H	
5255	ZANTHOXYLUM SIMULANS	A, H	
5256	ZEA MAYS	A, E, H	
5257	ZEAXANTHIN	A, E	
5258	ZEIN	E	
5259	ZINC	H	Only for use as an active homoeopathic ingredient. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'.
5260	ZINC AMINO ACID CHELATE	A, E, H	When used internally, zinc is a mandatory component of zinc amino acid chelate. The concentration of zinc in zinc amino acid chelate must be no more than 30%. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the

			medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5261	ZINC ASCORBATE	A, E, H	When used internally, zinc is a mandatory component of zinc ascorbate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5262	ZINC ASCORBATE MONOHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc ascorbate monohydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:

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			- (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)'.
5263	ZINC CHLORIDE	A, E, H	The concentration of zinc chloride in the medicine must be no more than 5%. When used internally, zinc is a mandatory component of zinc chloride. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5264	ZINC CITRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:

			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5265	ZINC CITRATE DIHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate dihydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5266	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. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc

			which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5267	ZINC DIASPARTATE	A	When used internally, zinc is a mandatory component of zinc diaspartate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5268	ZINC GLUCONATE	A, E, H	When used internally, zinc is a mandatory component of zinc gluconate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that

			effect).'
5269	ZINC GLYCINATE	A	When used internally, zinc is a mandatory component of Zinc glycinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5270	ZINC GLYCINATE MONOHYDRATE	A	When used internally, zinc is a mandatory component of Zinc glycinate monohydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'.

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5271	ZINC LACTATE	E	Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye. The concentration of zinc lactate in a medicine intended for topical use should be no more than 2%. The concentration of Zinc lactate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%. Zinc lactate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old. Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'.
5272	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. The concentration of Zinc lactate dihydrate in a medicine intended for topical use should be no more than 2%. The concentration of Zinc lactate dihydrate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%. Zinc lactate dihydrate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old. Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label:

			- (CHILD3) 'Use in children under 12 years is not recommended'.
5273	ZINC LYSINATE	A	When used internally, zinc is a mandatory component of Zinc lysinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5274	ZINC METHIONINE SULFATE	A	For topical use, the concentration of zinc methionine sulfate must be no more than 5%. When used internally, zinc is a mandatory component of zinc methionine sulfate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc

			which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5275	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. The concentration in the medicine must be no more than 0.1%.
5276	ZINC OXIDE	A, E, H	When used internally, zinc is a mandatory component of zinc oxide. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR -'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect). 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).
5277	ZINC PARA-PHENOLSULFONATE	E	The concentration of zinc para-phenolsulfonate in the medicine must not exceed 5%.

			When used internally, zinc is a mandatory component of zinc para-phenolsulfate. The percentage of zinc from zinc para-phenolsulfonate should be calculated based on the molecular weight of zinc para-phenolsulfonate. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect).
5278	ZINC STEARATE	E	When used internally, zinc is a mandatory component of zinc stearate. The percentage of zinc from zinc stearate should be calculated based on the molecular weight of zinc stearate.
5279	ZINC SUCCINATE	A, E, H	When used internally, zinc is a mandatory component of zinc succinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large

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			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).'
5280	ZINC SULFATE	A, E	For topical use, the concentration of zinc sulfate must be no more than 5%. For internal use, zinc is a mandatory component of zinc sulfate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5281	ZINC SULFATE HEPTAHYDRATE	A, E	For topical use, the concentration of zinc sulfate must be no more than 5%. For internal use, zinc is a mandatory component of zinc sulfate heptahydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no

			more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5282	ZINC SULFATE HEXAHYDRATE	A, E, H	For topical use, the concentration of zinc sulfate must be no more than 5%. For internal use, zinc is a mandatory component of zinc sulfate hexahydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5283	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%. When the medicine is for internal use, zinc is a mandatory component of zinc

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			sulfate monohydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5284	ZINC VALERATE	H	Only for use as an active homoeopathic ingredient. For internal use, zinc is a mandatory component of zinc valerate. The percentage of zinc from zinc valerate should be calculated based on the molecular weight of zinc valerate.
5285	ZINGERONE	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%.
5286	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: - (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'.
5287	ZIZIPHUS JUJUBA	A, H	
5288	ZIZIPHUS JUJUBA VAR. SPINOSA	A, H	
5289	ZIZYPHUS SATIVA	A, H	
5290	ZOSTERA MARINA	A, H	
5291	ZUCCHINI	E	

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Schedule 2—Repeals

Note: See section 7.

Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2021

1 The whole of the instrument

Repeal the instrument.