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

Note: See sections 5 and 6.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient Name	Purpose	Specific requirements
5065	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'.
5066	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 than

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			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.'
5067	ULEX EUROPAEUS	A, H	
5068	ULMUS AMERICANA	A, H	
5069	ULMUS CAMPESTRIS	A, H	
5070	ULMUS GLABRA	A, H	
5071	ULMUS MINOR	A, H	
5072	ULMUS PARVIFOLIA	A, H	
5073	ULMUS PUMILA	A, H	
5074	ULMUS RUBRA	A, H	
5075	ULTRALIDE	Е	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%.
5076	ULTRAMARINE BLUE	E	Permitted for use only as a colour for topical use.
5077	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%.

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			v orunie
5078	UMBELLULARIA CALIFORNICA	A, H	
5079	UNCARIA GAMBIR	A, H	
5080	UNCARIA RHYNCOPHYLLA	A, H	
5081	UNCARIA SINENSIS	A, H	
5082	UNCARIA TOMENTOSA	A, H	
5083	UNDARIA PINNATIFIDA	А, Н	Whole dried Undaria pinnatifida must not contain the holdfast.
			Only for use in oral medicines.
5084	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%.
5085	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%.
5086	UNDECENOIC ACID	Е	
5087	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%.

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5088	UNDECYLCRYLENE DIMETICONE	Е	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%.
5089	UNDECYLENAMIDE DEA	Е	
5090	UNDECYLENOYL PEG-5 PARABEN	Е	Only for use in topical medicines for dermal application.
5091	URANIUM NITRATE	Н	Only for use as an active homoeopathic ingredient.
5092	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).
5093	URTICA DIOICA	A, E, H	
5094	URTICA URENS	A, H	
5095	USNEA BARBATA	A, H	
5096	UVA URSI LEAF DRY	A, H	
5097	UVA URSI LEAF POWDER	A, E, H	
5098	VA/BUTYL MALEATE/ISOBORNYL ACRYLATE COPOLYMER	Е	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%.
5099	VACCARIA SEGATALIS	А, Н	
5100	VACCINIUM BRACTEATUM	A, H	
5101	VACCINIUM CORYMBOSUM	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%.
5102	VACCINIUM MACROCARPON	A, E, H	
5103	VACCINIUM MYRTILLOIDES	A, H	
5104	VACCINIUM MYRTILLUS	A, E, H	
5105	VACCINIUM OXYCOCCUS	A, H	
5106	VACCINIUM VITIS-IDAEA	А, Н	Beta-arbutin is a mandatory component of Vaccinium vitisidaea. 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%.
5107	VALENCENE	Е	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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5108	VALERALDEHYDE	Е	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%.
5109	VALERIAN DRY	А, Н	The requirement specified below applies to a medicine that contains the ingredient that is:
			- listed in the Register on or after 1 March 2023; or
			- released for supply on or after 1 March 2024:
			The following warning statement is required on the medicine label when the medicine is for oral use:
			(VALER) 'In rare cases, valerian 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.'
5110	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%.
5111	VALERIAN POWDER	А, Н	The requirement specified below applies to a medicine that contains the ingredient that is:
			- listed in the Register on or after 1 March 2023; or
			- released for supply on or after 1 March 2024:
			The following warning statement is required on the medicine label

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			when the medicine is for oral use:
			(VALER) 'In rare cases, valerian 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.'
5112	VALERIANA EDULIS	A, H	
5113	VALERIANA OFFICINALIS	А, Н	The requirement specified below applies to a medicine that contains the ingredient that is:
			- listed in the Register on or after 1 March 2023; or
			- released for supply on or after 1 March 2024:
			The following warning statement is required on the medicine label when the medicine is for oral use:
			(VALER) 'In rare cases, valerian 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.'
5114	VALERIANA SORBIFOLIA	А, Н	
5115	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%.
5116	VALINE	A, E	
5117	VANADIUM	Н	
5118	VANILLA	Е	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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			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5119	VANILLA DRY	A, E, H	
5120	VANILLA EXTRACT	Е	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%.
5121	VANILLA OLEORESIN	Е	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	VANILLA PLANIFOLIA	A, E, H	
5123	VANILLA POWDER	A, E, H	
5124	VANILLA TAHITENSIS	A, H	
5125	VANILLIC ACID	Е	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%.
5126	VANILLIN	E	
5127	VANILLIN ACETATE	E	Vanillin acetate 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 formulation containing vanillin acetate must

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

		Volume
		not be more than 5% of the total medicine.
		The maximum recommended daily dose of the medicine must not provide more than 1.8 micrograms of vanillin acetate.
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%.
VANILLYL ALCOHOL	Е	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%.
VAT RED 1	E	Permitted for use only as a colour for topical use.
VAT RED 1 ALUMINIUM LAKE	Е	Permitted for use only as a colour for topical use.
VAT RED 5	E	Permitted for use only as a colour for topical use.
VEGETABLE OIL	E	
VEGETABLE OIL	A	Only for use in oral medicines.
PHYTOSTEROL ESTERS		The medicine requires the following warning statement on the medicine label:
		- (PREGNT) 'Not recommended for use by pregnant and lactating
	VANILLYL ALCOHOL VAT RED 1 VAT RED 1 ALUMINIUM LAKE VAT RED 5 VEGETABLE OIL	VANILLYL ALCOHOL E VAT RED 1 E VAT RED 1 ALUMINIUM LAKE E VAT RED 5 E VEGETABLE OIL E VEGETABLE OIL A

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			women (or words to that effect).'
5135	VEIN	Н	Only for use as an active homoeopathic ingredient.
5136	VERATRALDEHYDE	Е	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%.
5137	VERATROL	Е	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%.
5138	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%.
5139	VERBASCUM DENSIFLORUM	A, H	
5140	VERBASCUM THAPSUS	A, H	
5141	VERBENA OFFICINALIS	A, H	
5142	VERBENA OIL	Е	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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5143	VERONICA CHAMAEDRYS	A, H	
5144	VERONICA OFFICINALIS	A, H	
5145	VERONICASTRUM VIRGINICUM	A, E, H	
5146	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%.
5147	VETIVER OIL	Е	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	VETIVERYL ACETATE	Е	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%.
5149	VIBURNUM OPULUS	A, E, H	
5150	VIBURNUM PRUNIFOLIUM	A, E, H	
5151	VICIA FABA	А, Н	Levodopa is a mandatory component of Vicia faba.

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			the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5152	VIGNA ANGULARIS VAR. ANGULARIS	А, Н	
5153	VIGNA RADIATA	A, H	
5154	VIGNA UMBELLATA	A, H	
5155	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%.
5156	VINCA MINOR	А, Н	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%
5157	VINCETOXICUM OFFICINALE	A, H	
5158	VINEGAR	Е	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%.
5159	VIOLA ODORATA	A, E, H	
5160	VIOLA TRICOLOR	A, H	
5161	VIOLA YEDOENSIS	A, H	
5162	VIOLET LEAF ABSOLUTE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5163	VIPER	Н	Only for use as an active homoeopathic ingredient.
5164	VISCUM ALBUM	A, E, H	
5165	VISCUM COLORATUM	A, H	
5166	VISCUM FLAVESCENS	A, H	
5167	VITELLARIA PARADOXA	A, E, H	
5168	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' (or words to that effect).
5169	VITEX NEGUNDO	A, H	
5170	VITEX ROTUNDIFOLIA	A, H	
5171	VITEX TRIFOLIA	A, H	
5172	VITIS VINIFERA	A, E, H	
5173	VITREOSCILLA CONCENTRATE	Е	Only for use in topical medicines for dermal application.
			The concentration in the medicine must be no more than 0.1%.
5174	VP/ACRYLATES/LAURYL METHACRYLATE COPOLYMER	Е	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%.

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5175	WAHLENBERGIA GRACILIS	A, H	
5176	WALNUT	E	
5177	WALNUT OIL	E	
5178	WATER MELON	Е	
5179	WHEAT	Е	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal.
5180	WHEAT BRAN	Е	Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal.
5181	WHEAT DEXTRIN	A, E	Gluten is a mandatory component of wheat dextrin.
			Only for use when the dosage form is capsule, tablet or pill.
5182	WHEAT GERM	E	Gluten is a mandatory component of Wheat germ when the route of administration is other than topical and mucosal.
5183	WHEAT GERM GLYCERIDES	Е	Gluten is a mandatory component of wheat germ glycerides when the route of administration is other than topical and mucosal.
5184	WHEAT LEAF	E	
5185	WHEAT STARCH	Е	When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch.
5186	WHEATGERM OIL	A, E, H	
5187	WHEY POWDER	Е	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5188	WHEY PROTEIN	E	Lactose is a mandatory component

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			of Whey protein when the route of administration is oral.
5189	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%.
5190	WHITE BEESWAX	E	
5191	WHITE HOREHOUND HERB DRY	A, H	
5192	WHITE HOREHOUND HERB POWDER	А, Н	
5193	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.
5194	WHOLE DRY MILK	Е	
5195	WIKSTROEMIA VIRIDIFLORA	A, H	
5196	WILD CARROT HERB DRY	A, E, H	
5197	WILD CARROT HERB POWDER	A, H	
5198	WILD CHERRY BARK DRY	A, H	
5199	WILD CHERRY BARK POWDER	A, H	
5200	WILD LETTUCE LEAF DRY	A, H	
5201	WILD LETTUCE LEAF POWDER	A, H	
5202	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%.

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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);

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			- (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'.
5203	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.
5204	WOLFIPORIA COCOS	A, E, H	
5205	WOOL ALCOHOLS	Е	Only for use in topical medicines for dermal application.
5206	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

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			existing from time to time.
5207	XANTHAN GUM	E	
5208	XANTHIUM SIBIRICUM	A, H	
5209	XANTHIUM STRUMARIUM	A, H	
5210	XANTHOMONA CAMPESTRIS	A, H	
5211	XEROPHYLLUM ASPHODELOIDES	A, H	
5212	XYLENE	Е	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%.
5213	XYLITOL	E	
5214	XYLOSE	Е	
5215	YAM	Е	
5216	YARROW HERB DRY	A, H	
5217	YARROW HERB POWDER	A, H	
5218	YEAST AUTOLYSATE	Е	
5219	YEAST DRIED	A, E, H	
5220	YELLOW 2G	Е	Permitted for use only as a colour for topical use.
5221	YELLOW BEESWAX	E	
5222	YELLOW MERCURIC OXIDE	Н	Only for use as an active homoeopathic ingredient.
5223	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.
5224	YLANG YLANG OIL	A, E, H	

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5225	YUCCA BACCATA	A, H	
5226	YUCCA ELATA	A, H	
5227	YUCCA FILAMENTOSA	A, H	
5228	YUCCA GLORIOSA	A, H	
5229	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 – beta damascone must not be more than 5% of the total medicine.
5230	ZANTHOXYLUM AMERICANUM	A, H	
5231	ZANTHOXYLUM BUNGEANUM	A, E, H	
5232	ZANTHOXYLUM CLAVA- HERCULIS	A, H	
5233	ZANTHOXYLUM NITIDUM	A, H	
5234	ZANTHOXYLUM PIPERITUM	A, H	
5235	ZANTHOXYLUM SIMULANS	A, H	
5236	ZEA MAYS	A, E, H	
5237	ZEAXANTHIN	A, E	
5238	ZEIN	Е	
5239	ZINC	Н	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

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			may be dangerous if taken in large amounts or for a long period (or words to that effect)'.
5240	ZINC AMINO ACID CHELATE	А, Е, Н	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).'
5241	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.

amounts or for a long period (or

When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the

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			words to that effect).'
5242	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:
			- (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)'.
5243	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

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may be dangerous if taken in large amounts or for a long period (or words to that effect).'

5244 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).'

5245 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

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			amounts or for a long period (or words to that effect).'
5246	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).'
5247	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).'

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5248	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).'
5249	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).'

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5250	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)'.
5251	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'.

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5252	ZINC LACTATE DIHYDRATE	Е	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'.
5253	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).'

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5254	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).'
5255	ZINC MYRISTATE	Е	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%.
5256	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

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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).
			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).
5257	ZINC PARA- PHENOLSULFONATE	E	The concentration of zinc paraphenolsulfonate 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 molecula weight of zinc paraphenolsulfonate.
			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 larg amounts or for a long period' (or words to that effect).
5258	ZINC STEARATE	E	When used internally, zinc is a mandatory component of zinc

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			stearate. The percentage of zinc from zinc stearate should be calculated based on the molecular weight of zinc stearate.
5259	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 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 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

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			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 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.' OF
			- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5262	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.

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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).'

5263 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 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).'

ZINC VALERATE 5264 Η Only for use as an active homoeopathic ingredient.

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			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.
5265	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%.
5266	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'.
5267	ZIZIPHUS JUJUBA	А, Н	
5268	ZIZIPHUS JUJUBA VAR. SPINOSA	A, H	
5269	ZIZYPHUS SATIVA	A, H	