

Regulatory Information Sheet

Approved Drug Colorants for Use in Canada*

I. Colorants approved for internal and external drug use

Color	Alternate Name	Color Index Number	CAS Number
Acid Fuchsin D	D&C Red #33	17200	3567-66-6
Alizarin Cyanine Green F	D&C Green #5	61570	4403-90-1
Allura Red AC	FD&C Red #40	16035	25956-17-6
Amaranth	Delisted FD&C Red #2	16185	915-67-3
Anthocyanin (Derived from juice expressed from fresh edible fruits or vegetables)	--	--	--
β -APO-8' Carotenal	--	40820	1107-26-2
Brilliant Blue FCF Sodium Salt	FD&C Blue #1	42090	3844-45-9
Brilliant Blue FCF Ammonium Salt	D&C Blue #4	42090	6371-85-2
Canthaxanthin	--	40850	514-78-3
Caramel	--	--	8028-89-5
Carbon Black	--	77266	1333-86-4
Carmine	--	75470	1390-65-4
Carmoisine	Delisted Ext. D&C Red #10	14720	3567-69-9
β -Carotene	--	40800	7235-40-7
Chlorophyll	--	75810	479-61-8
Eosin YS Acid Form	D&C Red #21	45380:2	15086-94-9
Eosin YS Sodium Salt	D&C Red #22	45380	17372-87-1
Erythrosine	FD&C Red #3	45430	16423-68-0
Fast Green FCF	FD&C Green #3	42053	2353-45-9
Flaming Red	D&C Red #36	12085	2814-77-9
Helindone Pink CN	D&C Red #30	73360	2379-74-0
Indigo	D&C Blue #6	73000	482-89-3
Indigotine	FD&C Blue #2	73015	860-22-0
Iron Oxides	Iron Oxide Orange	77489	1345-25-1
	Iron Oxide Red	77491	1309-37-1
	Iron Oxide Yellow	77492	51274-00-1
	Iron Oxide Black	77499	1317-61-9
Lithol Rubin B Sodium Salt	D&C Red #6	15850	5858-81-1
Lithol Rubin B Calcium Salt	D&C Red #7	15850:1	5281-04-9
Phloxine B Sodium Salt	D&C Red #28	45410	18472-87-2
Phloxine B Acid Form	D&C Red #27	45410:1	13473-26-2
Ponceau 4R	--	16255	2611-82-7

Color	Alternate Name	Color Index Number	CAS Number
Ponceau SX	FD&C Red #4	14700	4548-53-2
Quinoline Yellow WS	D&C Yellow #10	47005	8004-92-0
Riboflavin	--	--	83-88-5
Sunset Yellow FCF	FD&C Yellow #6	15985	2783-94-0
Tartrazine	FD&C Yellow #5	19140	1934-21-0
Titanium Dioxide	--	77891	13463-67-7

B. Preparations made by extending any of the above colors on a substratum of alumina, blanc fixe, gloss white, clay, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or any combination of these listed substances.

C. Preparations made by extending any sodium, potassium, aluminum, barium, calcium, strontium, or zirconium salt of any of the above colors on a substratum of alumina, blanc fixe, gloss white, clay, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or any combination of these listed substances.

II. Colorants approved for external drug use only

Color	Alternate Name	Color Index Number	CAS Number
Acid Violet 43	Ext. D&C Violet #2	60730	4430-18-6
Alizuroil Purple SS	D&C Violet #2	60725	81-48-1
Annatto	--	75120	--
Bismuth Oxychloride	--	77163	7787-59-9
Chromium Hydroxide Green	Pigment Green 18	77289	12001-99-9
Dibromofluorescein (Solvent Red 72)	D&C Orange #5	45370:1	596-03-2
Deep Maroon	D&C Red #34	15880:1	6417-83-0
Ferric Ferrocyanide	--	77510	14038-43-8
Guanine	--	75170	73-40-5
Manganese Violet	--	77742	10101-66-3
Mica	--	77019	12001-26-2
Orange II	D&C Orange #4	15510	633-96-5
Pyranine Concentrated	D&C Green #8	59040	6358-69-6
Quinizarin Green SS	D&C Green #6	61565	128-80-3
Toney Red	D&C Red #17	26100	85-86-9
Uranine Acid Form	D&C Yellow #7	45350:1	2321-07-5
Uranine Sodium Salt	D&C Yellow #8	45350	518-47-8
Zinc Oxide	--	77947	1314-13-2

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C. Preparations made by extending any sodium, potassium, aluminum, barium, calcium, strontium, or zirconium salt of any of the above colors on a substratum of alumina, blanc fixe, gloss white, clay, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or any combination of these listed substances.

*Based on the Canadian Department of Health's Food and Drug Regulations on Coloring Agents; Part C.01.040.2; Current to April 3, 2016; Last Amended on February 9, 2016.

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