



## Regulatory Information Sheet

### Approved Drug Colorants for Use in Canada\*

#### I. Colorants approved for internal and external drug use

A.

Color	Alternate Name	Color Index Number	CAS Number
Acid Fuchsin D	D&C Red No. 33	17200	3567-66-6
Alizarin Cyanine Green F	D&C Green No. 5	61570	4403-90-1
Allura Red AC	FD&C Red No. 40	16035	25956-17-6
Amaranth	Delisted FD&C Red No. 2	16185	915-67-3
Anthocyanin (Derived from juice expressed from fresh edible fruits or vegetables)	--	--	--
$\beta$ -APO-8'-Carotenal	--	40820	1107-26-2
Brilliant Blue FCF Sodium Salt	FD&C Blue No. 1	42090	3844-45-9
Brilliant Blue FCF Ammonium Salt	D&C Blue No. 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 No. 10	14720	3567-69-9
$\beta$ -Carotene	--	40800	7235-40-7
Chlorophyll	--	75810	479-61-8
Eosin YS Acid Form	D&C Red No. 21	45380:2	15086-94-9
Eosin YS Sodium Salt	D&C Red No. 22	45380	17372-87-1
Erythrosine	FD&C Red No. 3	45430	16423-68-0
Fast Green FCF	FD&C Green No. 3	42053	2353-45-9
Flaming Red	D&C Red No. 36	12085	2814-77-9
Helindone Pink CN	D&C Red No. 30	73360	2379-74-0
Indigo	D&C Blue No. 6	73000	482-89-3
Indigotine	FD&C Blue No. 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 No. 6	15850	5858-81-1
Lithol Rubin B Calcium Salt	D&C Red No. 7	15850:1	5281-04-9
Phloxine B Acid Form	D&C Red No. 27	45410:1	13473-26-2
Phloxine B Sodium Salt	D&C Red No. 28	45410	18472-87-2
Ponceau 4R	--	16255	2611-82-7
Ponceau SX	FD&C Red No. 4	14700	4548-53-2
Quinoline Yellow WS	D&C Yellow No. 10	47005	8004-92-0
Riboflavin	--	--	83-88-5
Sunset Yellow FCF	FD&C Yellow No. 6	15985	2783-94-0
Tartrazine	FD&C Yellow No. 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.

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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.

### II. Colorants approved for external drug use only

A.

Color	Alternate Name	Color Index Number	CAS Number
Acid Violet 43	Ext. D&C Violet No. 2	60730	4430-18-6
Alizuroil Purple SS	D&C Violet No. 2	60725	81-48-1
Annatto	--	75120	--
Bismuth Oxochloride	--	77163	7787-59-9
Chromium Hydroxide Green	Pigment Green 18	77289	12001-99-9
Deep Maroon	D&C Red No. 34	15880:1	6417-83-0
Dibromofluorescein (Solvent Red 72)	D&C Orange No. 5	45370:1	596-03-2
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 No. 4	15510	633-96-5
Pyranine Concentrated	D&C Green No. 8	59040	6358-69-6
Quinizarin Green SS	D&C Green No. 6	61565	128-80-3
Toney Red	D&C Red No. 17	45350:1	85-86-9
Uranine Acid Form	D&C Yellow No. 7	45350:1	2321-07-5
Uranine Sodium Salt	D&C Yellow No. 8	45350	518-47-8
Zinc Oxide	--	77947	1314-13-2

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.

\*Based on the Canadian Department of Health's Food and Drug Regulations on Coloring Agents; Part C.01.040.2; Current to November 8, 2018; Last Amended on October 23, 2018.

The information contained herein, to the best of our knowledge is true and accurate. Any recommendations or suggestions are made without warranty or guarantee, since the conditions of use are beyond our control. Any information contained herein is intended as a recommendation for use of our products so as not to infringe on any patent.

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