

Regulatory Information Sheet

Approved Drug Colourants Listed by the European Union

Note: Aluminum lakes prepared from colours mentioned in this list are also permitted

Colour	E Number	Colour Index Number	Alternate Names
Allura Red AC	E129	16035	FD&C Red #40
Aluminum	E173	77000	--
Annatto	E160b	75120	Bixin, norbixin
Amaranth	E123	16185	Delisted FD&C Red #2
Anthocyanins	E163	--	--
Beetroot Red	E162	--	Betanin
Beta APO-8'-Carotenal	E160e	40820	--
Beta APO-8'-Carotenoic acid ethyl ester	E160f	40825	--
Brilliant Black BN	E151	28440	Black PN
Brilliant Blue FCF	E133	42090	FD&C Blue #1
Brown FK	E154	--	--
Brown HT	E155	20285	--
Calcium Carbonate	E170	77220	--
Canthaxanthin	E161g	40850	--
Caramel,-Plain	E150a	--	--
Caramel,-Caustic Sulphite	E150b	--	--
Caramel,-Ammonia	E150c	--	--
Caramel, Sulphite Ammonia	E150d	--	--
Carmine	E120	75470	Carminic Acid, Cochineal
Carmoisine	E122	14720	Azorubine
Carotene		--	--
i. Mixed Carotenes	E160a (i)	75130	--
ii. Beta-Carotene	E160a (ii)	40800	--
Chlorophylls/Chlorophyllins		--	--
i. Chlorophylls	E140 (i)	75810	--
ii. Chlorophyllins	E140 (ii)	75815	--
Copper Complexes of Chlorophylls/Chlorophyllins			--
i. Copper Complexes of Chlorophylls	E141 (i)	75815	--
ii. Copper Complexes of Chlorophyllins	E141 (ii)		--
Erythrosine	E127	45430	FD&C Red #3
Gold	E175	77480	--
Green S	E142	44090	Acid Brilliant Green BS
Indigotine	E132	73015	FD&C Blue #2, Indigo Carmine

Colour	E Number	Colour Index Number	Alternate Names
Iron Oxides & Hydroxides	E172	77491	Iron Oxide Red
		77492	Iron Oxide Yellow
		77499	Iron Oxide Black
Litholrubine BK	E180	--	--
Lutein	E161b	--	--
Lycopene		--	--
i. Synthetic lycopene	E160D (i)	75125	Lycopene from chemical synthesis
ii. From red tomatoes	E160D (ii)		Natural Yellow 27
iii. From <i>Blakeslea trispora</i>	E160D (iii)		Natural Yellow 27
Paprika Extract	E160c	--	Capsanthin, Capsorubin
Patent Blue V	E131	42051	Acid Blue 3
Ponceau 4R	E124	16255	Cochineal Red A
Quinoline Yellow*	E104	47005	China Yellow
Riboflavin		--	--
i. Riboflavin	E101(i)	--	--
ii. Riboflavin-5'-phosphate	E101(ii)	--	--
Silver	E174	--	--
Sunset Yellow FCF	E110	15985	FD&C Yellow #6, Orange Yellow S
Tartrazine	E102	19140	FD&C Yellow #5
Titanium Dioxide	E171	77891	--
Turmeric	E100	75300	Curcumin
Vegetable Carbon Black	E153	77268:1	Carbo Medicinalis Vegetalis

This list is derived from Annex 1 of Directive 94/36/EC, colours permitted for use in foodstuffs. Directive 2009/35/EC (superceding 78/25/EEC) states that colourants mentioned in this Annex are permitted for use in medicinal products.

*This is not D&C Yellow #10. Although the C.I. numbers are the same, the dyes differ in composition. Quinoline Yellow is primarily the disulfonated quinoline dye, whereas D&C Yellow #10 is the monosulfonated color. Quinoline Yellow is not accepted for use in the U.S.; conversely, D&C Yellow #10 cannot be used in the EU.

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.

© 2010 Colorcon, Inc. The information contained in this document is proprietary to Colorcon, Inc. and may not be used or disseminated inappropriately.

Global Headquarters
Colorcon
275 Ruth Road, Harleysville, PA 19438
Tel: +1 215.256.7700 Fax: +1 215.256.7799 Website: www.colorcon.com
© BPSI Holdings LLC, 2010. All trademarks, except where noted, are property of BPSI Holdings LLC.

