



# Regulatory Information Sheet

## Provisionally Listed Color Additives Subject to U.S. Certification\*

Color	Common Name	Color Index Number	CAS Number	21 CFR References		
				Food	Drug	Cosmetic
FD&C Lakes	Lakes	See Individual Color	See Individual Color	<a href="#">82.51</a>	<a href="#">82.51</a>	<a href="#">82.51</a>
D&C Lakes	Lakes	See Individual Color	See Individual Color	--	<a href="#">82.1051</a>	<a href="#">82.1051</a>
Ext. D&C Lakes	Lakes	See Individual Color	See Individual Color	--	<a href="#">82.2051</a>	<a href="#">82.2051</a>
FD&C Blue #1 Lake	Brilliant Blue FCF	42090:2	68921-42-6	<a href="#">82.101</a>	<a href="#">82.101</a>	<a href="#">82.101</a>
FD&C Blue #2 Lake	Indigotine	73015:1	16521-38-3	<a href="#">82.102</a>	<a href="#">82.102</a>	<a href="#">82.102</a>
D&C Blue #4 Lake	Alphazurine FG	42090	6371-85-3	--	<a href="#">82.1104</a>	<a href="#">82.1104</a>
FD&C Green #3 Lake	Fast Green FCF	42053	2353-45-9	<a href="#">82.203</a>	<a href="#">82.203</a>	<a href="#">82.203</a>
D&C Green #5 Lake	Alizarin Cyanine Green F	61575	4403-90-1	--	<a href="#">82.1205</a>	<a href="#">82.1205</a>
D&C Green #6 Lake	Quinizarine Green SS	61565	128-80-3	--	<a href="#">82.1206</a>	<a href="#">82.1206</a>
D&C Orange #4 Lake	Orange II	15510:2	633-56-5	--	<a href="#">82.1254</a>	<a href="#">82.1254</a>
D&C Orange #5 Lake	Dibromofluorescein	45370:2	596-03-2	--	<a href="#">82.1255</a>	<a href="#">82.1255</a>
D&C Orange #10 Lake	Diiodofluorescein	45425:2	38577-97-8	--	<a href="#">82.1260</a>	<a href="#">82.1260</a>
D&C Orange #11 Lake	Erythrosine Yellowish Na	45425:2	38577-97-8	--	<a href="#">82.1261</a>	<a href="#">81.1261</a>
FD&C Red #4 Lake	Ponceau SX	14700	4548-53-2	<a href="#">82.304</a>	<a href="#">82.304</a>	<a href="#">82.304</a>
D&C Red #6 Lake	Lithol Rubin B	15850:2	17852-98-1	--	<a href="#">82.1306</a>	<a href="#">82.1306</a>
D&C Red #7 Lake	Lithol Rubin B Ca	15850:1	5281-04-9	--	<a href="#">82.1307</a>	<a href="#">82.1307</a>
D&C Red #17 Lake	Toney Lake	26100	85-86-9	--	<a href="#">82.1317</a>	<a href="#">82.1317</a>
D&C Red #21 Lake	Tetrabromofluorescein	45380:3	15086-94-9	--	<a href="#">82.1321</a>	<a href="#">82.1321</a>
D&C Red #22 Lake	Eosine	45380:3	17372-87-1	--	<a href="#">82.1322</a>	<a href="#">82.1322</a>
D&C Red #27 Lake	Tetrachlorotetra-Bromofluorescein	45410:2	13473-26-2	--	<a href="#">82.1327</a>	<a href="#">82.1327</a>
D&C Red #28 Lake	Phloxine B	45410:2	18472-87-02	--	<a href="#">82.1328</a>	<a href="#">82.1328</a>
D&C Red #30 Lake	Helindone Pink CN	73360	2379-74-0	--	<a href="#">82.1330</a>	<a href="#">82.1330</a>
D&C Red #31 Lake	Brilliant Lake Red R	15800:1	6371-76-2	--	<a href="#">82.1331</a>	<a href="#">82.1331</a>
D&C Red #33 Lake	Acid Fuchsine	17200	3567-66-6	--	<a href="#">82.1333</a>	<a href="#">82.1333</a>
D&C Red #34 Lake	Lake Bordeaux B	15880:1	6417-83-0	--	<a href="#">82.1334</a>	<a href="#">82.1334</a>
D&C Red #36 Lake	Flaming Red	12085	2814-77-9	--	<a href="#">82.1336</a>	<a href="#">82.1336</a>
D&C Violet #2 Lake	Alizuroil Purple SS	60725	81-48-1	--	<a href="#">82.1602</a>	<a href="#">82.1602</a>
FD&C Yellow #5 Lake	Tartrazine	19140:1	12225-21-7	<a href="#">82.705</a>	<a href="#">82.705</a>	<a href="#">82.705</a>
FD&C Yellow #6 Lake	Sunset Yellow FCF	15985:1	15790-07-5	<a href="#">82.706</a>	<a href="#">82.706</a>	<a href="#">82.706</a>
D&C Yellow #7 Lake	Fluorescein	45350:1	2321-07-5	--	<a href="#">82.1707</a>	<a href="#">82.1707</a>
Ext. D&C Yellow #7 Lake	Napthol Yellow S	10316	846-70-8	--	<a href="#">82.2707a</a>	<a href="#">82.2707a</a>
D&C Yellow #8 Lake	Uranine	45350	518-47-8	--	<a href="#">82.1708</a>	<a href="#">82.1708</a>
D&C Yellow #10 Lake	Quinoline Yellow WS	47005:1	68814-04-0	--	<a href="#">82.1710</a>	<a href="#">82.1710</a>

\*Based on 21 CFR 201.8. Restrictions may exist limiting the use of some of these colors to specific applications (i.e. external drug use only, etc.). Additionally, there may be quantitative limits for the use of some colors. The specific 21 CFR reference for each color should be reviewed to determine potential restriction status.



---

## Regulatory Information Sheet

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](http://www.colorcon.com)  
© BPSI Holdings LLC, 2010. All trademarks, except where noted, are property of BPSI Holdings LLC.

