



## Regulatory Information Sheet

### List of Permanently Listed Color Additives Subject to U.S. Certification\*

| Color                          | Common Name                       | Color Index Number | CAS Number | 21 CFR References      |                          |                          |                         |
|--------------------------------|-----------------------------------|--------------------|------------|------------------------|--------------------------|--------------------------|-------------------------|
|                                |                                   |                    |            | Food                   | Drug                     | Cosmetic                 | Medical Devices         |
| D&C Black No. 2                | Carbon Black                      | 77266              | 1333-86-4  | --                     | --                       | <a href="#">74.2052</a>  | --                      |
| D&C Black No. 3                | Bone Black                        | 77267              | 8021-99-6  | --                     | --                       | <a href="#">74.2053</a>  | --                      |
| FD&C Blue No. 1                | Brilliant Blue FCF                | 42090              | 2650-18-2  | <a href="#">74.101</a> | <a href="#">74.1101</a>  | <a href="#">74.2101</a>  | --                      |
| FD&C Blue No. 2                | Indigotine                        | 73015              | 860-22-0   | <a href="#">74.102</a> | <a href="#">74.1102</a>  | --                       | <a href="#">74.3102</a> |
| D&C Blue No. 4                 | Alphazurine FG                    | 42090              | 6371-85-3  | --                     | <a href="#">74.1104</a>  | <a href="#">74.2104</a>  | --                      |
| D&C Blue No. 6                 | Indigo                            | 73000              | 482-89-3   | --                     | --                       | --                       | <a href="#">74.3106</a> |
| D&C Blue No. 9                 | Indanthrene Blue                  | 69825              | 130-20-1   | --                     | <a href="#">74.1109</a>  | --                       | --                      |
| D&C Brown No. 1                | Resorcin Brown                    | 20170              | 1320-07-6  | --                     | --                       | <a href="#">74.2151</a>  | --                      |
| FD&C Green No. 3               | Fast Green FCF                    | 42053              | 2353-45-9  | <a href="#">74.203</a> | <a href="#">74.1203</a>  | <a href="#">74.2203</a>  | --                      |
| D&C Green No. 5                | Alizarin Cyanine Green F          | 61570              | 4403-90-1  | --                     | <a href="#">74.1205</a>  | <a href="#">74.2205</a>  | --                      |
| D&C Green No. 6                | Quinizarine Green SS              | 61565              | 128-80-3   | --                     | <a href="#">74.1206</a>  | <a href="#">74.2206</a>  | <a href="#">74.3206</a> |
| D&C Green No. 8                | Pyranine Concentrated             | 59040              | 6358-69-6  | --                     | <a href="#">74.1208</a>  | <a href="#">74.2208</a>  | --                      |
| Orange B                       | --                                | 19235              | --         | <a href="#">74.250</a> | --                       | --                       | --                      |
| D&C Orange No. 4               | Orange II                         | 15510              | 633-96-5   | --                     | <a href="#">74.1254</a>  | <a href="#">74.2254</a>  | --                      |
| D&C Orange No. 5               | Dibromofluorescein                | 45370:1            | 596-03-2   | --                     | <a href="#">74.1255</a>  | <a href="#">74.2255</a>  | --                      |
| D&C Orange No. 10              | Diiodofluorescein                 | 45425:1            | 3329-19-9  | --                     | <a href="#">74.1260</a>  | <a href="#">74.2260</a>  | --                      |
| D&C Orange No. 11              | Erythrosine Yellowish Na          | 45425              | 38577-97-8 | --                     | <a href="#">74.1261</a>  | <a href="#">74.2261</a>  | --                      |
| [Phthalocyaninato (2-)] Copper | Copper Phthalocyanine             | 74160              | 147-14-8   | --                     | --                       | --                       | <a href="#">74.3045</a> |
| FD&C Red No. 3                 | Erythrosine                       | 45430              | 16423-68-0 | <a href="#">74.303</a> | <a href="#">74.1303</a>  | --                       | --                      |
| FD&C Red No. 4                 | Ponceau SX                        | 14700              | 4548-53-2  | --                     | <a href="#">74.1304</a>  | <a href="#">74.2304</a>  | --                      |
| D&C Red No. 6                  | Lithol Rubin B                    | 15850              | 5858-81-1  | --                     | <a href="#">74.1306</a>  | <a href="#">74.2306</a>  | --                      |
| D&C Red No. 7                  | Lithol Rubin B Ca                 | 15850:1            | 5281-04-9  | --                     | <a href="#">74.1307</a>  | <a href="#">74.2307</a>  | --                      |
| D&C Red No. 17                 | Toney Red                         | 26100              | 85-86-9    | --                     | <a href="#">74.1317</a>  | <a href="#">74.2317</a>  | <a href="#">74.3230</a> |
| D&C Red No. 21                 | Tetrabromofluorescein             | 45380:2            | 15086-94-9 | --                     | <a href="#">74.1321</a>  | <a href="#">74.2321</a>  | --                      |
| D&C Red No. 22                 | Eosine                            | 45380              | 17372-87-1 | --                     | <a href="#">74.1322</a>  | <a href="#">74.2322</a>  | --                      |
| D&C Red No. 27                 | Tetrachlorotetra-Bromofluorescein | 45410:1            | 13473-26-2 | --                     | <a href="#">74.1327</a>  | <a href="#">74.2327</a>  | --                      |
| D&C Red No. 28                 | Phloxine B                        | 45410              | 18472-87-2 | --                     | <a href="#">74.1328</a>  | <a href="#">74.2328</a>  | --                      |
| D&C Red No. 30                 | Helindone Pink CN                 | 73360              | 2379-74-0  | --                     | <a href="#">74.1330</a>  | <a href="#">74.2330</a>  | --                      |
| D&C Red No. 31                 | Brilliant Lake Red R              | 15800:1            | 6371-76-2  | --                     | <a href="#">74.1331</a>  | <a href="#">74.2331</a>  | --                      |
| D&C Red No. 33                 | Acid Fuchsine                     | 17200              | 3567-66-6  | --                     | <a href="#">74.1333</a>  | <a href="#">74.2333</a>  | --                      |
| D&C Red No. 34                 | Lake Bordeaux B                   | 15880:1            | 6417-83-0  | --                     | <a href="#">74.1334</a>  | <a href="#">74.2334</a>  | --                      |
| D&C Red No. 36                 | Flaming Red                       | 12085              | 2814-77-9  | --                     | <a href="#">74.1336</a>  | <a href="#">74.2336</a>  | --                      |
| D&C Red No. 39                 | Alba Red                          | 13058              | 6371-55-7  | --                     | <a href="#">74.1339</a>  | --                       | --                      |
| FD&C Red No. 40                | Allura Red AC                     | 16035              | 25956-17-6 | <a href="#">74.340</a> | <a href="#">74.1340</a>  | <a href="#">74.2340</a>  | --                      |
| FD&C Red No. 40 Lake           | Allura Red AC                     | 16035:1            | 68583-95-9 | <a href="#">74.340</a> | <a href="#">74.1340</a>  | <a href="#">74.2340</a>  | --                      |
| Citrus Red No. 2               | --                                | 12156              | 6358-53-8  | <a href="#">74.302</a> | --                       | --                       | --                      |
| D&C Violet No. 2               | Alizuril Purple SS                | 60725              | 81-48-1    | --                     | <a href="#">74.1602</a>  | <a href="#">74.2602</a>  | <a href="#">74.3602</a> |
| Ext. D&C Violet No. 2          | Alizarin Violet                   | 60730              | 4430-18-6  | --                     | --                       | <a href="#">74.2602a</a> | --                      |
| FD&C Yellow No. 5              | Tartrazine                        | 19140              | 1934-21-0  | <a href="#">74.705</a> | <a href="#">74.1705</a>  | <a href="#">74.2705</a>  | --                      |
| FD&C Yellow No. 6              | Sunset Yellow FCF                 | 15985              | 2783-94-0  | <a href="#">74.706</a> | <a href="#">74.1706</a>  | <a href="#">74.2706</a>  | --                      |
| D&C Yellow No. 7               | Fluorescein                       | 45350:1            | 2321-07-5  | --                     | <a href="#">74.1707</a>  | <a href="#">74.2707</a>  | --                      |
| Ext. D&C Yellow No. 7          | Naphthol Yellow S                 | 10316              | 846-70-8   | --                     | <a href="#">74.1707a</a> | <a href="#">74.2707a</a> | --                      |



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|-------------------|---------------------|--------------------|------------|-------------------|-------------------------|-------------------------|-------------------------|
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| D&C Yellow No. 8  | Uranine             | 45350              | 518-47-8   | --                | <a href="#">74.1708</a> | <a href="#">74.2708</a> | --                      |
| D&C Yellow No. 10 | Quinoline Yellow WS | 47005              | 8004-92-0  | --                | <a href="#">74.1710</a> | <a href="#">74.2710</a> | <a href="#">74.3710</a> |
| D&C Yellow No. 11 | Quinoline Yellow SS | 47000              | 8003-22-3  | --                | <a href="#">74.1711</a> | <a href="#">74.2711</a> | --                      |

\*Based on 21 CFR current as of November 16, 2018. 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(s) for each color should be reviewed to determine potential restriction status.

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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