

**FOLKS!
DON'T MISS
THIS!**



**FDA revoked FD&C Red No. 3's approval,
leaving only FD&C Red No. 40 in foods ...**

**Where are the other 38 red
colorants?**



There are two types of color additives:

Don't require batch certification

They have names like
“beta-carotene” or
“iron oxides”

Require batch certification

They have names like
“FD&C Red No. 3” or
“D&C Orange No. 5”

The certified colors' name is made-up by FDA and has three pieces.

Use	Predominant Shade	Number
FD&C	Red	No. 3
Citrus	Red	No. 2
FD&C	Yellow	No. 6
D&C	Orange	No. 5
Ext. D&C	Violet	No. 2



Understanding the Shade:

It's a bit self-explanatory, red is red, violet is violet, and so on. This was selected instead of the previous “common” names.

The list is as follows:

Red shades:

107. Amaranth.

56. Ponceau 3 R.

517. Erythrosin.

Orange shade:

85. Orange I.

Yellow Shade:

4. Naphthol yellow S.

Green shade:

435. Light green S. F. yellowish.

Blue shade:

692. Indigo disulfoacid.

Understanding the Number:

Each colorant in the shade is assigned a sequential number.

So Red No. 40 is the 40th red shade certified color.

PART 8—COLOR ADDITIVES

Subpart C—Listing of Color Additives
for Food Use Subject to Certification

Subpart E—Listing of Color Additives
for Drug Use Subject to Certification

FD&C RED No. 40

The Commissioner of Food and Drugs, on the basis of a petition submitted by Allied Chemical Corp., Specialty Chemicals Division, c/o Hazleton Laboratories, Inc., Post Office Box 30, Falls Church, Va. 22046, and other relevant material, finds that FD&C Red No. 40 (identified below) is safe for use in food and drugs under the conditions prescribed in this order and that certification is necessary for the protection of the public health. In the petition and the notice of filing thereof which was published June 27, 1970 (35 F.R. 10529), the additive's name was "Allura Red AC"; however, the petitioner has requested that the additive be known as "FD&C Red No. 40."

Understanding the Use Code:

The code indicates the products that could include the colorant (at least historically).

Code	Translation
FD&C	Food, drugs, and cosmetics
Citrus	Citrus (oranges really)
D&C	Drugs or cosmetics
Ext. D&C	External drugs or cosmetics

Understanding the Use Code:

The code is now largely meaningless because the law change after FDA developed this system in 1939.

D&C Black No. 2 While there's "D" for drug, it cannot be used any drug product

FD&C Blue No. 2 While there's "C" for cosmetic, it cannot be used in any cosmetics, only food, ingestible drugs, and surgical sutures

Simplifying the Name

FDA sometimes permits to a certified color being named only by its **Shade** and **Number**.

A Food Labeling Guide

Guidance for Industry

C3. What ingredient listing is used for artificial colors?

Answer: It depends on whether the artificial color is a certified color:

Certified colors: List by specific or abbreviated name such as “FD&C Red No. 40” or “Red 40.”

Non-certified colors: List as “artificial color,” “artificial coloring,” or by their specific common or usual names such as “caramel coloring” and “colored with beet juice.”

21 CFR 101.22(k)(1) and (2), 21 CFR 74

Simplifying the Name ... Sometimes

Yet elsewhere FDA continues to expect the use code as part of the name, even though it is really a historic legacy.

The Over-the-Counter Drug Facts Label

FDA requires a standard label of important drug information for all over-the-counter (OTC) drug products

Drug Facts (continued)	
Other information	■ store at 20-25°C (68-77°F) ■ protect from excessive moisture
Inactive ingredients	D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

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