

FCC/USP Survey on Synthetic Food Color Additives

Background and Purpose: The *Food Chemicals Codex (FCC)* is a compendium of internationally recognized testing standards owned by US Pharmacopeia for assessing the authenticity, quality, purity, and thus safety of food ingredients. In an effort to update and modernize *FCC* testing standards for synthetic food color additives, *FCC* is seeking up-to-date information from leading producers of these ingredients on the chemical composition and analytical test methods for the eighteen color additives listed below in Table 1, along with samples of individual color additives or impurities. Information collected by *FCC* will be used to update existing monograph testing standards for these color additives or for the creation of new testing standards for those not already in *FCC*. Samples collected by *FCC* will be used by USP labs to evaluate candidate analytical methods, and to develop USP reference materials to aid *FCC* users in carrying out monograph tests.

Reason to Participate: Participation in this project is an opportunity for leading color additive manufacturers to help establish the high-bar of quality in *FCC* monograph standards.

Table 1: Food Color Additives of Interest

Allura Red AC	Azorubine	Patent Blue V
Amaranth	Erythrosine	Ponceau 4R
Brilliant Black PN	Fast Green FCF	Quinoline Yellow
Brilliant Blue FCF	Green S	Red 2G
Brown FK	Indigotine	Sunset Yellow FCF
Brown HT	Lithol Rubine BK	Tartrazine

Survey Instructions: For each synthetic food color additive that you produce, please provide as much information on the attached questions as possible to the Jeff Moore at FCC/USP.

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PARTICIPANT INFORMATION FORM

Name:

Title:

Company:

Address:

Email:

Phone Number:

SURVEY FORM– PLEASE FILL OUT SEPARATE FORM FOR EACH COLOR ADDITIVE

1. Color Additive Name:
2. Chemical and Technical Information:
 - a. Please briefly describe the chemistry you use to synthesize this color additive (e.g., condensation of X and Y and sulfonation of the resultant product with concentration sulfuric acid).
 - b. What are the chemical identities (including isomers) of the principal coloring constituent(s) in the food-grade material that you produce?
 - c. What are the chemical identities of any subsidiary coloring constituent(s) in the food-grade material that you produce?
 - d. What are the chemical identities of any organic impurities (“Organic compounds other than coloring matters”, “Uncombined intermediates and products of side reactions”) in the food-grade material that you produce?
3. Analytical Methods:
 - a. Beyond JECFA and FCC monograph methods, do you have available any modern analytical methods (HPLC, CE, etc) for assessing the identity, purity, and organic impurities of this color additive that could be provided to FCC? These could be your in-house R&D methods, routine QA methods, literature methods, etc. If so, please indicate the types of methods you can provide.
 - b. Do you have available analytical methods to measure the principal uncoloured components of this color additive that could be provided to FCC? For example for the percentage of material not accounted for in the Assay specification that may represent sodium chloride and/or sodium sulphate as the
4. Reference materials:
 - a. Can you provide FCC with an approximately 500 g sample of your color additive for method R&D purposes, and potentially for development into a new authentic USP reference material?
 - b. Do you have available any high purity (>95%) samples that can be provided to USP of any of the principal coloring constituents and organic impurities (“organic compounds other than coloring matters”, “uncombined intermediates and products of side reactions) of this color additive? USP is seeking these materials for development in USP Reference Standards support the monograph test procedures. If so, please list names and amounts available.

5. Production:

- a. What is your annual production of this color additive?