

Commentary

Food Chemicals Codex (FCC), Eleventh Edition, Third Supplement

September 3, 2019

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts (CoE Rules), and except as provided in Section 8.01(e) *Immediate Standards*, USP publishes proposed revisions to the *Food Chemicals Codex (FCC)* for public review and comment in the *FCC Forum (FCCF)*, USP's venue for providing public notice and receiving public comment on an *FCC* proposed standard. After comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to effective status or be republished in *FCCF* for further notice and comment, in accordance with the CoE Rules. In cases when proposals advance to effective status without republication in the *FCCF*, a summary of comments received and the FIEC's responses are published in the *Commentary* section of the [FCC microsite](#) at the time the revision is published.

The *Commentary* is not part of the text of the monograph or general test or assay. Rather, it explains the basis of the FIEC's response to public comments. If there is a difference between the contents of the *Commentary* section and the monograph or general test or assay, the text of the monograph prevails. In case of a dispute or question of interpretation, the language of the monograph text, alone and independent of the *Commentary*, prevails.

For further information, contact:

USP Executive Secretariat
U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790 USA
execsec@usp.org

Comments were received for the following when they were proposed in the Food Chemicals Codex (FCC):

- [Allyl Cinnamate](#)
- [Amaranth](#)
- [Azorubine](#)
- [Brilliant Black PN](#)
- [Carthamus Yellow](#)
- [Appendix VII -- Differentiation of Plant Oils Using Chemical Markers](#)
- [Olive Oil, Refined](#)
- [Quinoline Yellow](#)

No Comments were received for the following when they were proposed in the Food Chemicals Codex (FCC):

- *β-Apo-8'-Carotenal*
- *β-Carotene from Blakeslea trispora*
- *β-Carotene*
- *Appendix XIV – Biobased Content of Food Ingredients (Based on ASTM D6866 Method B)*
- *Calcium Phosphate, Dibasic*
- *Calcium Phosphate, Monobasic*
- *Calcium Phosphate, Tribasic*
- *Canthaxanthin*
- *Diatomaceous Earth*
- *Appendix XVIII -- Guidance on Developing and Validating Non-Targeted Methods for Adulteration Detection*
- *Identity Standards (Introductory Text)*
- *Locust (Carob) Bean Gum*
- *Lycopene, Synthetic*
- *Maritime Pine Extract*
- *Neohesperidin Dihydrochalcone*
- *Oxygen*
- *Polyglycerol Polyricinoleic Acid*
- *TBHQ*
- *Test Solutions (TS) and Other Reagents*

Monograph/Section(s): Allyl Cinnamate

Expert Committee: Food Ingredients

Expert Committee (EC)-initiated Change #1: The term “Allyl beta-phenylacrylate” was deleted from the list of synonyms in the *Chemical Information* section because it is not a common synonym for this ingredient.

Monograph/Section(s): Amaranth/Multiple Sections

Expert Committee: Food Ingredients

EC-initiated Change #1: The color in the *Description* was changed from “reddish brown to dark reddish brown” to “red-brown to dark red-brown” for clarification.

EC-initiated Change #2: The note “D needs to be expressed as a decimal and not a %” was added to the calculation for *Subsidiary Coloring Matters* for clarification.

EC-initiated Change #3: *System suitability* criteria originally referenced from the test for *Uncombined Intermediates and Products of Side Reactions* was added to *Subsidiary Coloring Matters* to avoid confusion.

EC-initiated Change #4: The chemical name “7-Hydroxy-1,3-naphthalenetrisulfonic acid” was changed to “7-hydroxy-1,3,6-naphthalenetrisulfonic acid” in *Table 2* under *Uncombined Intermediates and Products of Side Reactions* to correct a typographical error.

Monograph/Section(s): Azorubine/Multiple Sections

Expert Committee: Food Ingredients

EC-initiated Change #1: The *Acceptance criteria* was changed from “NMT 3%” to “NMT 1%” in *Subsidiary Coloring Matters* due to general safety concerns.

EC-initiated Change #2: The note “D needs to be expressed as a decimal and not a %” was added to the calculation for *Subsidiary Coloring Matters* for clarification.

EC-initiated Change #3: *System suitability* criteria originally referenced from the test for *Uncombined Intermediates and Products of Side Reactions* was added to *Subsidiary Coloring Matters* to avoid confusion.

Monograph/Section(s): Brilliant Black PN/Multiple Sections

Expert Committee: Food Ingredients

EC-initiated Change #1: The note “D needs to be expressed as a decimal and not a %” was added to the calculation for *Subsidiary Coloring Matters* for clarification.

EC-initiated Change #2: *System suitability* criteria originally referenced from the test for *Uncombined Intermediates and Products of Side Reactions* was added to *Subsidiary Coloring Matters* to avoid confusion.

EC-initiated Change #3: A footnote stating “For confirmation of impurity peaks, commercially available reference materials may be used” was added to *Organic Impurities-Uncombined Intermediates and Products of Side Reactions* to assist users.

Monograph/Section(s): Carthamus Yellow/Multiple Sections

Expert Committee: Food Ingredients

Commenters: 1

Comment Summary #1: The commenter requested removal of CAS number 1228508-31-3 from safflomin B in the *Chemical Identification* section because it is not correct.

Response: Comment incorporated.

Comment Summary #2: The commenter requested replacing “drying the extract” in with “It is a flavonoid mixture obtained by extracting the corolla (petals) of *Carthamus*”

tinctorius L. with water or slightly acidified water and concentrating the extract. The extract may be dried” in the *Description* to add clarification.

Response: Comment incorporated.

Comment Summary # 3: The commenter requested replacing “consists of sugars, salts, and/or proteins naturally occurring in” with “consist of carbohydrates, proteins, minerals, fiber and flavonoids extracted from” in the *Description* to add clarification.

Response: Comment incorporated.

Comment Summary # 4: The commenter requested replacing the proposed relative response times with an example fingerprint chromatogram in *Identification A* since relative response times may change based on the specific chromatographic systems and conditions used.

Response: Comment partially incorporated. The relative response times were maintained as they provide useful information on identification of the chemical substances. An example chromatogram of carthamus yellow was added *Identification A*.

Comment Summary # 5: The commenter requested revising the *Acceptance criteria* in the test for *Lead limit* from “5 mg/kg” to “2 mg/kg” in recognition that exposure to lead needs to be minimized because of its health impact.

Response: Comment not incorporated. The Expert Committee will consider future revisions to this monograph upon the receipt of the necessary supporting data.

Monograph/Section(s): Appendix VII: Differentiation of Plant Oils Using Chemical Markers

Expert Committee: Food Ingredients

EC-initiated Change #1: The term “derive” was changed to “derivatize” throughout the text to accurately describe the process.

EC-initiated Change #2: The term “BSA+TMCS” was changed to “N,O-Bis(trimethylsilyl)acetamide+chlorotrimethylsilane (BSA+TMCS)” in the *System suitability solution* for clarification of the proper reagent.

Monograph/Section(s): Olive Oil, Refined/Multiple Sections

Expert Committee: Food Ingredients

EC-initiated Change #1: Instructions for preparing and using an internal standard were added to *E. Fatty Acid Composition* to assist users.

EC-initiated Change #2: Spelling errors were corrected in numerous places throughout the text.

EC-initiated Change #3: The term “*Reference standard solution*” was changed to “*Internal standard solution*” throughout the text of *F. Sterols* to avoid confusion based on the way the solution is used in the test.

EC-initiated Change #4: A *Standard solution* was added to *G. Squalene Content and Linolenic Acid to Squalene Ratio* to assist users.

EC-initiated Change #5: Based on additional information and data received, the *Acceptance criteria* for the ratio of linolenic acid content to squalene content was

changed from “NMT 1” to “NMT 4.5” in *G. Squalene Content and Linolenic Acid to Squalene Ratio*.

EC-initiated Change #6: The linoleic acid range provided in the *Acceptance criteria Note* in *G. Squalene Content and Linolenic Acid to Squalene Ratio* was changed from “400-2000 mg/kg” to “4000-20000 mg/kg” to correct an error.

EC-initiated Change #7: Based on additional information received, the *Note* within *I. Waxes, Suitability check* related to conditioning the column was updated from “Heat gradually to a temperature at least 20° above the operating temperature and at least 20° less than the maximum specified temperature for the eluant used” to “Heat gradually until a temperature of 350° is reached after approximately 4 h. Maintain this temperature for at least 2 h, then regulate the apparatus to the operating conditions (regulate gas flow, light flame, connect to electronic recorder, regulate oven temperature for column, regulate detector, etc.).”

EC-initiated Change #8: The following text was added to *Additional Considerations, Hexanal and Nonanal, Discussion of results* in order to provide clarification of test results for users “The presence of both hexanal and nonanal indicates oxidation has occurred”.

Monograph/Section(s): Quinoline Yellow/Multiple Sections

Expert Committee: Food Ingredients

EC-initiated Change #1: The chemical names, structure, and formula weight were revised in the *Chemical Information* section to represent the exact chemical substances represented by the monograph.

EC-initiated Change #2: The maximum absorbance was changed from “412 nm” to “413 ± 2 nm” in the *Identification* test based on additional information and data received.