

Commentary Food Chemicals Codex (FCC), Thirteenth Edition, Second Supplement

March 1, 2023

In accordance with the *Rules and Procedures of the 2020-2025 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 cases 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 FCC Forum:

- Cholic Acid
- Paprika Oleoresin
- Schizochytrium Oil

No comments were received for the following when they were proposed in the FCC Forum:

- Allyl Disulfide
- Allyl Mercaptan
- Allyl Sulfide
- Appendix II Physical Tests and Determinations, Water Determination
- Appendix III Chemical Tests and Determinations, Elemental Impurities by ICP
- Aspartame-Acesulfame Salt
- Biphenyl
- Folic Acid
- Galacto-oligosaccharides
- Isomaltooligosaccharides
- Potato Protein
- Sodium Molybdate Dihydrate
- Spice Oleoresins
- Whey Protein Concentrate
- Whey Protein Isolate

Monograph/Section(s): Cholic Acid/Description

Expert Committee: Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter requested that the solubility stated in the *Description* be revised from "one g dissolves in about 30 mL of alcohol or acetone and in about 7 mL of glacial acetic acid" to "one gram in 33 mL of alcohol and one gram in 6.5 mL of glacial acetic acid," to provide more precise solubility parameters.

Response: Comment not incorporated. The *Description* section of *FCC* monographs does not convey specifications. Statements related to solubility in the *Description* are intended to be informational only and may be approximate. The existing solubility information is accurate without revision.

Monograph/Section(s): Paprika Oleoresin/Title

Expert Committee: Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter requested that the *Title* of this monograph be revised from "Paprika Oleoresin" to "Oleoresin Paprika" for consistency with ingredient names referenced in the *Spice Oleoresins* monograph and to avoid confusion. **Response:** Comment not incorporated. The requested new *Title* "Oleoresin Paprika" is already included in the synonyms and is a searchable term within *FCC/Forum Online*. The current *Title* is also consistent with the naming convention applied to at least one other *FCC* monograph, *Turmeric Oleoresin*.

Monograph/Section(s): Schizochytrium Oil/Description

Expert Committee: Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter indicated that the phrase "followed by solvent extraction or aqueous extraction methods" in the *Description* is confusing, because "aqueous extraction" falls within the definition of "solvent extraction." The commenter requested rephrasing the statement to more specifically describe extraction methods used in the manufacture of this ingredient.

Response: Comment incorporated. The section was revised to state "followed by extraction" to avoid repetition or placing limits on allowed extraction techniques.