



Commentary

Food Chemicals Codex (FCC), Twelfth Edition, Second Supplement

March 1, 2021

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 USP.org website 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.

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

- [Calcium L-Threonate](#)
- [Neotame](#)
- [Olive Oil, Extra Virgin and Virgin](#)
- [Olive Oil, Refined](#)

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

- Advantame
- Ammonium Salts of Phosphatidic Acid
- Appendix V: Enzyme Assay
- Appendix VII: Fats and Related Substances
- Appendix VIII: Oleoresins
- Appendix XVI: Protein-Based Ingredients
- Appendix XVII: Food Fraud Mitigation Guidance
- Disodium Inosinate
- Formic Acid

Monograph/Section(s): Calcium L-Threonate/Chemical Information
Expert Committee: Food Ingredients
No. of Commenters: 0

Expert Committee-Initiated Change #1: The synonym “butanoic acid, 2,3,4-trihydroxy-calcium salt (2:1), (2R,3S)” was added to this monograph for consistency with online sources of chemical information and nomenclature.

Monograph/Section(s): Neotame/Specific Tests & Description
Expert Committee: Food Ingredients
No. of Commenters: 1

Comment Summary #1: The commenter requested a sample size of 0.50 g be added to the test for *Water* to ensure consistency with the 2020 *USP-NF* monograph and to improve accuracy of the test for products with very low levels of water.

Committee Response: Comment incorporated.

Comment Summary #2: The commenter requested to revise the solubilities provided in the *Description* as follows: remove solubility in ethyl acetate as it is not an appropriate solvent for Neotame; revise the solubility in water from “sparingly soluble” to “sparingly to slightly soluble”; revise the solubility in alcohol from “very soluble” to “freely to very soluble”. The proposed solubility descriptors are consistent with the commenter’s internal data.

Committee Response: Comment incorporated.

Monograph/Section(s): Olive Oil, Extra Virgin and Virgin/Identification
Expert Committee: Food Ingredients
No. of Commenters: 1

Comment Summary #1: The commenter submitted a series of comments requesting changes to various *Acceptance criteria* within the *Identification* section.

Committee Response: Comments not incorporated. The comments and supporting data were not received in sufficient time to be considered by the Expert Committee. The Expert Committee will consider the proposed changes as potential revisions in a future *FCC Forum*.

Monograph/Section(s):	Olive Oil, Refined/Additional Considerations
Expert Committee:	Food Ingredients
No. of Commenters:	0

Expert-Committee Initiated Change #1: To minimize the potential impact of shifts in retention times, the following text was added to the *Analysis* under *Hexanal and Nonanal*: “Inject the standard at the beginning and end of every batch of samples to observe any retention time shifts.”

Expert-Committee Initiated Change #2: To clarify the chromatograms provided, the following parenthetical text was added to the caption for *Figure 3* in the test for *Chlorophyll Breakdown Products*: “The top image is for a virgin olive oil having a PPP < 2.0 and the bottom image is for a refined olive oil having no PP or PPP.”