



**COMMENTARY—Food Chemicals Codex (FCC)
FCC Eight Edition,
February 24, 2012**

In accordance with USP's Rules and Procedures of the 2010-2015 Council of Experts (Rules), USP publishes all proposed revisions to the *Food Chemicals Codex (FCC)* for public review and comment in the *FCC Forum (FCCF)*. The *FCCF* is USP's free online journal for providing notice and receiving public comment on *FCC standards*. After public comments are considered and incorporated as the Monographs–Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to effective status and be published in *FCC* or, republished on the *FCCF* website for further notice and public comment in accordance with USP's Rules. When a proposed revision advances to effective status and is published in *FCC*, a summary of all comments received and the FIEC's responses are posted in the *Commentary* section of the USP website (www.usp.org).

The *Commentary* section below 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 content 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* section prevails.

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No comments were received for the following proposals:

Monographs

Amaranth
Appendix III - Chemical Tests and Determinations
Azorubine
BHA
Cassia Oil
DHA from Algal (*Ulkenia*) Oil
Ferrous Citrate
Gellan Gum

Monographs (continued)

Ponceau 4R

Sodium Molybdate Dihydrate

Stearyl Alcohol

Xanthan Gum

COMMENTARY— FCC Eight Edition

Monograph/Sections: (+)-Limonene/ Other requirements, angular rotation

Expert Committee: Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter requested maintaining the lower range for (+)-limonene of + 96°, and only to increase the maximum to the proposed +125° to reflect the variety of (+)-limonene currently on the market and allow the acceptance criteria to represent synthetic limonene as well as the isolated extract from orange oil. Data confirming the proposed range was provided.

Response: Comment incorporated.

Monograph/Sections: Sodium Phosphate, Dibasic/ Specific Tests

Expert Committee: Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter indicated that the names of the recommended ion exchange chromatograph (AG11 ICS 2000, ICS 3000 Dionex Corporation, Sunnyvale, CA, or equivalent) and guard column (Ionpac, Dionex Corporation, Sunnyvale, CA, or equivalent) were incorrect and could result in an incorrect recommendation of the chromatographic system. The names were proposed to be changed to Ion exchange chromatograph ICS 2000, ICS 3000 Dionex Corporation (Sunnyvale, CA), or equivalent; and Ionpac AG11 (Dionex Corporation, Sunnyvale, CA), or equivalent; respectively.

Response: Comment incorporated

Monograph/Sections: Cyclamic Acid / Assay

Expert Committee: Food Ingredients

No. of Commenters: 0

Expert Committee Initiated Change #1: The FIEC changed the equivalence for 0.1 N sodium hydroxide in the *Analysis* section of the *Assay* from 17.82 mg/mL of NaOH to 17.92 mg/mL of NaOH to correctly reflect the molecular weight of cyclamic acid.

Monograph/Sections: DHA from Algal (*Cryptocodinium*) Oil / Identification

Expert Committee: Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter requested that the entire fatty acid composition table be removed from the monograph on the basis that international regulatory approvals for the ingredient are based solely on the DHA content. Further basis for removal offered by the commenter was the belief that describing the ingredient by the fatty acid composition gives preference to the manufacturer whose product was the basis of monograph development and that the fatty acid composition gives no added assurance to the safety of the ingredient.

Response: Comment not incorporated. The FIEC believes that the fatty acid composition is necessary for proper identification of the ingredient.

Monograph/Sections: Neohesperidine Dihydrochalcone / Organic Impurities, Assay

Expert Committee: Food Ingredients

No. of Commenters: 0

Expert Committee Initiated Change #1: The FIEC removed *Standard solution B* from the *Related Compounds* test because of the lack of commercial availability of the compound known as Neohesperidine Dihydrochalcone Related Compound B. The calculation of the related compound was adjusted to be based on the solution originally proposed as *Standard solution C*.

Expert Committee Initiated Change #2: The FIEC changed the *Mobile phase* in the *Assay* to “Acetonitrile and *Solution A* (20:80)” to correct an erratum in the original proposal.

Expert Committee Initiated Change #3: The FIEC added clarification to the preparation of the *System suitability solution* in the *Assay* by adding “boiling” before “water bath” in the second sentence.