



Commentary

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

September 1, 2018

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 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.

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 Forum (FCCF):

- [Allyl Disulfide](#)
- [Caramel](#)
- [Citric and Fatty Acid Esters of Glycerol](#)
- [Hesperidin](#)
- [Krill Oil](#)
- [Potassium Diacetate](#)
- [Taurine](#)

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

- Allyl Mercaptan
- Caffeine
- Carmine
- Citric acid
- Disodium guanylate
- Disodium inosinate
- Lycopene Extract from Tomato
- Lycopene from Blakeslea Trispora
- Potassium Lactate Solution

Monograph/Sections: Allyl Disulfide/Description

Expert Committee: Food Ingredients

Expert Committee-initiated Change: The word “lacrymator” was deleted because this ingredient is not a lacrymator.

Monograph/Section(s): Caramel/Multiple Sections

Expert Committee: Food Ingredients

Inorganic Impurities:

Expert Committee-initiated Change #1: The existing *Acceptance criteria* in the *Arsenic* and *Lead* tests were maintained in order to harmonize with other international standards.

Additional Information:

Expert Committee-initiated Change #2: The existing tests for *Identification of Classes*, *Identification Tests for Classes*, and *2-Acetyl-4(5)-Tetrahydroxybutylimidazole (THI)* were maintained in order to harmonize with other international standards and in recognition that THI is a toxic substance.

Monograph/Sections: Citric and Fatty Acid Esters of Glycerol/Description
Expert Committee: Food Ingredients
Expert Committee-initiated Change: The color of the ingredient was changed from “yellowish to light brown” to “white to off-white” to reflect the full color range of the substance of commerce.

Monograph/Sections: Hesperidin/Description
Expert Committee: Food Ingredients
Expert Committee-initiated Change: The color of the ingredient was changed from “white or light brown to yellowish” to “white to light-yellow brown” to reflect the full color range of the substance of commerce.

Monograph/Sections: Krill Oil//Multiple Sections
Expert Committee: Food Ingredients
Expert Committee-initiated Change #1: The specifications for alpha-linolenic and stearidonic acids were maintained in the *Identification*. Though these are minor fatty acids, they are important in identifying authentic krill oil.
Expert Committee-initiated Change #2: The color of the ingredient was changed from “opaque reddish” to “opaque red-orange to red-brown” to reflect the full color range of the substance of commerce.

Monograph/Sections: Potassium Diacetate/Multiple Sections
Expert Committee: Food Ingredients
Expert Committee-initiated Change #1: The chemical structure was replaced for clarification.
Expert Committee-initiated Change #2: The *Description* was updated to provide more detailed information about the compound. Specifically the phrase “Potassum Dacetate occurs as a white, hygroscopic, crystalline solid” was revised to “Potassium Diacetate is a molecular compound of potassium acetate and acetic acid. It occurs as a white, hygroscopic, crystalline solid.”
Expert Committee-initiated Change #3: The *Acceptance criteria* in the *Assay* methods were changed from “36.0%-38.0%” to “36%-38%” in the test for *Free Fatty Acid* and from “61.0%-64.0%” to “61%-64%” in the test for *Potassium Acetate* to harmonize with other international standards.
Expert Committee-initiated Change #4: The *Acceptance Criteria* in the *Readily Oxidizable Substances* test was changed from “NMT 0.2%” to “NMT 0.1%” to harmonize with other international standards.
Expert Committee-initiated Change #5: The *Acceptance Criteria* in the *Water* test was changed from “NMT 2.0%” to “NMT 1%” to harmonize with other international standards.

Monograph/Sections: Taurine/Inorganic Impurities

Expert Committee: Food Ingredients

Expert Committee-initiated Change: In the test for *Ammonium*, the instructions for preparation of the *Sample solution* were revised to accurately explain the apparatus in Figure 1.