



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

March 1, 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 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 Forum (FCCF):

- [Acetylated Monoglycerides](#)
- [Magnesium Dihydrogen Diphosphate](#)

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

- Bentonite
- *Bifidobacterium Animalis* SSP. *Lactis* BI-07
- *Bifidobacterium Animalis* SSP. *Lactis* BI-04
- *Bifidobacterium Animalis* SSP. *Lactis* HN019
- Fluoride Limit Test
- Glycerin
- *Glycerol ester of Wood Rosin*
- *Lactobacillus Acidophilus* LA-14
- *Lactobacillus Paracasei* LPC-37
- *Lactobacillus Rhamnosus* HN001
- Meso-Zeaxanthin
- Mono- and Diglycerides
- Potassium Pyrophosphate
- Sodium Polyphosphates, Glassy
- Sodium Pyrophosphate
- Sodium Trimetaphosphate
- Xanthan Gum

Monograph/Section(s): Acetylated Monoglycerides/Specific Tests

Expert Committee: Food Ingredients

Commenters: 1

Comment Summary #1: The commenter suggested limiting the sample weight range used to prepare the *Sample solution* from “45.00 – 200.00 mg” to “45.00 – 50.00 mg” in the *Total Acetic Acid* test.

Response: Comment incorporated.

Comment Summary #2: The commenter suggested removing the *Analysis* text in the *Total Acetic Acid* test.

Response: Comment not incorporated. The text within *Analysis* is necessary to conduct the test.

Comment Summary #3: The commenter suggested replacing the proposed calculation (and its legend). The calculation as proposed is incorrect and will not give the intended result. Alternate calculations were proposed by the commenter.

Response: Comment incorporated. The proposed calculation and legend from *Total Acetic Acid* test were replaced with “ $CU = (rU - a) / b$ where CU = concentration of the analyte (sodium acetate) in the *Sample solution* (mg/mL); rU = peak area of the analyte from the *Sample solution*; a = offset/intercept; b = slope. Calculate the percentage of acetic acid in the portion of sample taken: $Result = (CU \times F \times V \times 100\%) / W$ where W =

weight of sample used to prepare the *Sample solution* (mg); F = factor converting sodium acetate to acetic acid, 0.732; V = volume of *Sample solution* (22 mL).”

Monograph/Section(s): Magnesium Dihydrogen Diphosphate/Multiple Sections

Expert Committee: Food Ingredients

Commenters: 1

Comment Summary #1: The commenter requested the title of the proposed monograph, “Magnesium Dihydrogen Diphosphate”, be changed to “Magnesium Acid Pyrophosphate” to be consistent with other monographs for similar ingredients in *FCC*.

Response: Comment incorporated.

Comment Summary #2: The commenter requests the deletion of tests and specifications for *Aluminum* and *Cadmium* from *Inorganic Impurities* to maintain consistency with the other *FCC* phosphate monographs.

Response: Comment incorporated.

Comment # 3: The commenter indicated the limits for *Arsenic* and *Lead* should be consistent with other *FCC* phosphate limits (NMT 3 mg/kg Arsenic and NMT 2 mg/kg Lead).

Response: Comment not incorporated. The data provided indicate the product is able to meet the proposed specifications.

Comment Summary #4: The commenter requested the *Calcium* test be moved from *Inorganic Impurities* to *Specific Tests*.

Response: Comment incorporated.

Expert Committee-initiated Change #1: The chemical structure was revised to reflect the “+2” on Mg rather than the current “+” which is not correct.