



**Commentary — Food Chemicals Codex (FCC)  
Eighth Edition, First Supplement  
August 31, 2012**

In accordance with USP's 2010-2015 Rules and Procedures of the 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)*, USP's journal for public notice and comment for *FCC*. After comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to official status or be republished in *FCCF* for further notice and comment, in accordance with the Rules. In cases when proposals advance to official status without republication in *FCCF*, a summary of comments received and the FIEC's responses are published in the *Commentary* section of the USP Web site at the time the revision is published.

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 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* section prevails.

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**No comments were received for the following proposals:**

***Monographs***

2-Acetylpyridine  
Allyl Anthranilate  
Allyl Butyrate  
Allyl Cinnamate  
Allyl Cyclohexane Valerate  
Allyl Disulfide  
Allyl Mercaptan  
Allyl Sulfide  
Alpha-Amylcinnamaldehyde Dimethyl Acetal

**Monographs (continued)**

Alpha-Amylcinnamyl Acetate  
Alpha-Amylcinnamyl Alcohol  
Alpha-Amylcinnamyl Formate  
Beta-Caroteneusp Dextrose  
Calcium Benzoate  
Cinnamic Acid  
Enzyme Preparations Used In Food Processing  
Eucalyptol  
Green S  
Hydroxypropyl Cellulose  
Methyl Salicylate  
Methylbenzyl Acetate  
Monk Fruit Extract  
Polydextrose  
Potassium Benzoate  
Proteolytic Activity, Bacterial (PC)  
Proteolytic Activity, Fungal (SAP)  
Quinoline Yellow  
Sodium Benzoate  
Sodium Selenate Anhydrous  
Sucrose  
Whey  
Whey Protein Concentrate  
Whey Protein Isolate  
Whey, Reduced Lactose  
Whey, Reduced Minerals

**COMMENTARY— FCC Eighth Edition, First Supplement**

**Monograph/Sections:** Chromic Chloride/ Impurities, Inorganic Impurities

**Expert Committee:** Food Ingredients

**No. of Commenters:** 1

**Comment summary #1:** The commenter requested harmonizing the limits for this material to both the general limits for trace metals in the General Chapter <232> *Elemental Impurities – Limits of USP-NF* and to any general limits that the European Union and ICH may also be considering. The commenter also suggested that because chromic chloride is usually added at 45 µg in multivitamins, the daily consumption of any impurities in chromic chloride should be very small, much less than the proposed limits in <232>. Related, the commenter indicated that the cost of testing for these impurities could be too high for potential users of this ingredient.

**Response:** Comment not incorporated. Data for supporting the commenter’s proposal were not provided. Additionally, while potential exposure to these impurities through a multivitamin could justify higher limits, this ingredient is also

used in foods where its dosage and exposure can be difficult to control (i.e. infant formula, snacks, energy bars, cereal, etc.). Therefore, lower limits are recommended in the *FCC*.

**Monograph/Section:** Sodium Potassium Tripolyphosphate / Chemical Information

**Expert Committee:** Food Ingredients

**No. of Commenters:** 1

**Comment Summary #1:** The commenter requested updating the INS number from 452(vi) to 451(iii) in order to reflect the most current classification by the Codex Alimentarius' Codex Committee on Food Additives.

**Response:** Comment incorporated.

**Monograph/Sections:** Trisodium Diphosphate (Trisodium Pyrophosphate) / Multiple Sections

**Expert Committee:** Food Ingredients

**No. of Commenters:** 1

**Comment summary #1:** The commenter requested changing the name of the monograph to Trisodium Pyrophosphate because the term "Trisodium Pyrophosphate" is more consistent with the name of this type of phosphates in the *FCC*. The commenter indicated that the term "diphosphate" is not commonly used in the US and other *FCC* jurisdictions; pyrophosphate is the term specifically used for similar substances in the 21 CFR Part 182; Trisodium Pyrophosphate is the term used for this material in jurisdictions other than the EU (China, Australia-New Zealand, Canada, Japan, Mexico); and multiple jurisdictions that use the *FCC* utilize the term pyrophosphate. Lastly, the General Provisions chapter states that the titles of *FCC* monographs are based in the common or usual names for a material.

**Response:** Comment incorporated.

**Comment Summary #2:** The commenter requested deleting "Acid Trisodium Pyrophosphate" from the synonyms list and suggested either adding "Trisodium Pyrophosphate" or putting the latter as the primary name and adding "Trisodium Diphosphate" as a synonym. See comment summary #1 for the rationale.

**Response:** Comment incorporated. "Trisodium Pyrophosphate" will be used as the primary name and "Trisodium Diphosphate" as the synonym.

**Comment Summary #3:** The commenter requested adding the information about the pH of a 1% aqueous solution to the *Description* section, and eliminating it from the *Specific Tests* section. The commenter also requested adding the following wording "The pH of a 1:100 aqueous solution is about 7," to eliminate a specific pH range. Both recommendations would make this monograph consistent with other *FCC* monographs for phosphates.

**Response:** Comment incorporated. The pH range was moved to the *Description* section, however, the specific range was maintained because this specific pH range constitutes a descriptor of the material according to its GRAS package and the Expert Committee directive.

**Comment Summary #4:** The commenter requested making the significant figures of the *Acceptance Criteria* of the *Assay* consistent, noting that other *FCC* monographs for phosphates have only one significant figure.

**Response:** Comment incorporated.

**Comment Summary #5:** The commenter requesting changing the *Acceptance Criteria* for cadmium from 1 mg/kg to 3 mg/kg based on the *FCC* monograph for phosphoric acid, which is the main raw material for this phosphate. The commenter indicated that through calculations, trisodium pyrophosphate could potentially contain up to 2.4 mg/kg of cadmium if the phosphoric acid contained 3 mg/kg cadmium (the *FCC* specification limit).

**Response:** Comment incorporated.

**Comment Summary #6:** The commenter requested removing the specification and acceptance criteria for mercury, as it is not present in phosphoric acid or its salts, and is not added during the manufacturing process of phosphates.

**Response:** Comment incorporated.

**Comment Summary #7:** The commenter requested changing the acceptance criteria of fluoride to NMT 50 mg/kg in order to make the criteria consistent with fluoride specification limits for other sodium phosphates in the *FCC* (e.g., tetrasodium pyrophosphate and sodium acid pyrophosphate). Moreover, the fluoride limits proposed would be difficult or impossible to meet with current manufacturing practices and raw materials sources.

**Response:** Comment incorporated.

**Comment Summary #8:** The commenter suggested lowering the acceptance criteria for lead to NMT 2 mg/kg in order to be consistent with the exposure expected from similar phosphates in the *FCC*.

**Response:** Comment incorporated

**Comment Summary #9:** The commenter suggested removing Loss on Drying (LOD), because the LOD provided for the monohydrate is incorrect, and LOD does not add more information beyond the Loss on Ignition.

**Response:** Comment incorporated.

**Monograph/Sections:** Appendix XV: Microbial Food Products Including Probiotics / Multiple Sections

**Expert Committee:** Food Ingredients

**No. of Commenters:** 1

**Comment Summary #1:** The commenter requested a number of editorial changes to remove ambiguity and improve clarity.

**Response:** Comment incorporated.

**Expert Committee Initiated Change #1:** The Food Ingredients Expert Committee made a number of editorial clarifications, particularly in areas related to regulatory issues. The majority of these edits were within the sections entitled “Uses of Microbial Food Cultures in Food Production” and “Safety.”