

COMMENTARY—*Food Chemicals Codex (FCC) 6 First Supplement*

Revision proposals published in *Food Chemicals Codex (FCC) Forum* often elicit public comments that are forwarded to the Food Ingredients Expert Committee for review and response. In accordance with the Rules and Procedures of the 2005-2010 Council of Experts, revision proposals can advance to publication with minor modifications, as needed, without requiring further public review. In such cases a summary of comments are published on the USP website. For those proposals that require further revision and republication in *FCC Forum*, a summary of the comments and the Expert Committee's responses will be included in the briefing that accompanies each article.

The *Commentary* section is not part of the text of the monograph or general test or assay. Rather, it explains the basis of the Expert Committee'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.

For further information, contact:
The USP Executive Secretariat
U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790 USA
execsec@usp.org

Comments received supporting the following proposals:

Isomalt
Polyvinylpyrrolidone
Polyvinylpyrrolidone
Maltitol
Maltitol Syrup
Mannitol
Sorbitol
Sorbitol Solution
Appendix III-Chemical Tests and Determinations (*Fluoride Limit Test*)

No comments received for the following proposals:

General Tests and Assays

Appendix II-Physical Tests and Determinations

Monographs

(E),(E)-2,4-Decadienal	(E),(Z)-2,6-Nonadienal
(E),(E)-2,4-Heptadienal	(E)-2-Decenal
(E),(E)-2,4-Nonadienal	(E)-2-Dodencen-1-al

COMMENTARY—Food Chemicals Codex (FCC) 6 First Supplement

No comments received for the following proposals, continued

Monographs, continued

(E)-2-Hexen-1-al	D-Limonene
(E)-2-Nonenal	Ethoxyquin
(E)-2-Octen-1-al	Ethyl Cellulose
(Z)-4-Decenal	Ferrous Sulfate
1,3,5-Undecatriene	Ferrous Sulfate, Dried
10-Undecenal	Food Starch, Modified
2,3-Heptandione	Food Starch, Unmodified
2,3-Pentanedione	Furfural
2,6-Dimethyl-5-Heptenal	Gamma-Terpinene
2-Ethylbutyraldehyde	Gum Arabic
2-Methyl Butanal	Heptanal
2-Methylundecanal	Hexanal
2-Phenylpropionaldehyde	Hydroxycitronellal
2-Tridecenal	Iron, Carbonyl
3,4-Dimethyl 1,2-Cyclopentandione	Iron, Reduced
3,5,5-Trimethyl Hexanal	Isobutyraldehyde
3-Methyl Butanal	Lauryl Aldehyde
3-Methylthiopropionaldehyde	L-Limonene
3-Phenylpropionaldehyde	Manganese Sulfate
4-Hydroxy-2,5-Dimethyl-3(2H)-Furanone	Mannitol
5-Methyl 2-Phenyl 2-Hexenal	Myrcene
5-Methyl Furfural	Nonanal
5-Methyl-2-Isopropyl-2-Hexenal	Octanal
Acetaldehyde	Phenylacetaldehyde
Alpha-Amylcinnamaldehyde	Propionaldehyde
Alpha-Methylcinnamaldehyde	P-Tolualdehyde
Alpha-Phellandrene	Salicyladehyde
Alpha-Pinene	Sodium Carboxymethyl Cellulose, Enzymatically Hydrolyzed
Alpha-Terpinene	Sodium Lignosulfonate
Benzaldehyde	Sodium Metaphosphate, Insoluble
Beta-Caryophyllene	Sodium Phosphate, Dibasic
Beta-Pinene	Sodium Phosphate, Monobasic
Butyraldehyde	Sodium Polyphosphates, Glassy
Calcium Lignosulfonate	Sodium Pyrophosphate
Calcium Silicate	Stannous Chloride
Camphene	Tara Gum
Cinnamaldehyde	TBHQ
Citral	Tolualdehyde, Mixed Isomers
Citronellal	Trehalose
Copovidone	Undecanal
Cuminic Aldehyde	Valeraldehyde
Cyclamen Aldehyde	Zinc Oxide
Decanal	Zinc Sulfate
Diacetyl	
Diocetyl Sodium Sulfosuccinate	

COMMENTARY—*Food Chemicals Codex (FCC) 6 First Supplement*

Monograph/Section(s): Carrageenan/Multiple Sections

Expert Committee(s): Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter requested removing the *Total inorganic impurities* test and acceptance criteria because 1) they are aware of no published data that shows a synergistic toxicological effect of heavy metals, 2) the test creates inconsistency with the *Joint FAO/WHO Expert Committee on Food Additives (JECFA)* specifications, and 3) the test could result in a trade barrier for food products containing the additive.

Response: Comment incorporated.

Expert Committee Initiated Change #1: The Expert Committee added a note to the *Description* section describing carrageenan sample dispersion techniques, which may be helpful to analysts unfamiliar with handling carrageenan materials.

Expert Committee Initiated Change #2: The Expert Committee added the *Gum constituents identification* test to the *Identification* section to aid in the identification of carrageenan and to maintain consistency with the *JECFA (2007) Carrageenan Monograph*.

Expert Committee Initiated Change #3: The Expert Committee corrected the *Mercury* test *Sample weight* and the *Sample solution* final dilution volume to ensure testing in the linear range for this procedure.

Expert Committee Initiated Change #4: The Expert Committee removed the *Microbial limits* test procedure and acceptance criteria because the test created inconsistency between the monograph and the *Microbial Attributes (Policy)* published in the *Food Chemicals Codex, Fifth Edition*, and because the Expert Committee did not receive data that justified the necessity of the specification.

Monograph/Section(s): Isomalt/Multiple Sections

Expert Committee(s): Food Ingredients

No. of Commenters: 2

Comment Summary #1: The commenter requested addition of the structure(s) for isomalt to the *Chemical information* section.

Response: Comment incorporated. The Expert Committee added structures for 1,6-GPS and 1,1-GPM, which is consistent with the structures provided in the *JECFA (1996) Isomalt Monograph*.

Comment Summary #2: The commenter requested changing the *Function* section from “sweetener, bulking agent, Anticaking agent, glazing agent” to read: “nutritive sweetener, texturizer, formulation aid, surface finishing agent, stabilizer and thickener.”

Response: Comment incorporated.

Comment Summary #3: The commenter requested revising the *Lead test* to incorporate different furnace conditions including temperatures and gas flow rates.

Response: Comment not incorporated because scientific justification for the change was not provided. The Expert Committee is willing to consider revising the method in a future *Food Chemicals Codex Forum* if scientific justification is provided.

COMMENTARY—*Food Chemicals Codex (FCC) 6 First Supplement*

Comment Summary #4: The commenter requested changing the *Nickel* test to use a graphite furnace atomic absorption spectroscopy method rather than the proposed atomic absorption method proposed.

Response: Comment not incorporated because scientific justification for the change was not provided. The Expert Committee is willing to consider revising the method in a future *Food Chemicals Codex Forum* if scientific justification is provided.

Comment Summary #5: Two commenters requested revising the *Reducing sugars* section by replacing the proposed gravimetric method with a titrimetric method. Using the titrimetric method would 1) create consistency with maltitol and other polyol monographs in the *Food Chemicals Codex* and *United States Pharmacopeia-National Formulary (USP-NF)* and 2) yield higher values for reducing sugar content. One of the commenters requested the titrimetric method require dissolving the sample in 10 mL of water rather than 3 mL of water due to the low solubility of isomalt.

Response: Comment not incorporated because the Expert Committee considered the requested changes too significant to incorporate without further public review and comment. The proposed revisions will be provided for public comment in a future *Food Chemicals Codex Forum*.

Monograph/Section(s): Noncrystallizing Sorbitol Solution/Multiple Sections

Expert Committee(s): Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter requested that the factor in the Assay calculation be changed from 100 to 10,000. This missing factor of 100 is necessary to convert to percentage and is consistent with the same formula used in other polyol monographs in *USP-NF*. The commenter also suggested that the formula divide by (100-W) instead of multiply by (100-W) to correct the calculation for the water content.

Response: Comment incorporated.

Comment Summary #2: The commenter requested that the *Lead* calculation be revised to directly calculate on the anhydrous basis, instead of requiring the user to make this correction which is implied in the "...calculated on the anhydrous basis" in the acceptance criteria.

Response: Comment incorporated.

Comment Summary #3: The commenter requested that the *Nickel* calculation be revised to directly calculate on the anhydrous basis, instead of requiring the user to make this correction which is implied in the "...calculated on the anhydrous basis" in the acceptance criteria.

Response: Comment incorporated.

Monograph/Section(s): Phosphoric Acid/Inorganic Impurities

Expert Committee(s): Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter requested revising the *Fluoride* test in other (unspecified) phosphate monographs by adding instructions to use *Buffer solution B*.

Response: Comment not incorporated because no supporting data was provided. The Expert Committee is willing to consider a revision to the *Fluoride* analyses in other phosphate monographs if supporting data is provided.

COMMENTARY—*Food Chemicals Codex (FCC) 6 First Supplement*

Comment Summary #2: The commenter requested replacing the *Fluoride* test with a standard addition method.

Response: Comment not incorporated because no supporting data was provided. The Expert Committee is willing to consider a revision to the *Fluoride* method if supporting data is provided.

Monograph/Section(s): Pullulan/Multiple Sections

Expert Committee(s): Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter requested changing the *pH* acceptance criteria from “4.5-6.5” to “5.0-7.0” to be consistent with the 65th JECFA (2005) Pullulan Monograph.

Response: Comment incorporated.

Comment Summary #2: The commenter requested changing the *Mono-, Di-, and Oligosaccharides* test to be consistent with the Pullulan Monograph proposed in the *United States Pharmacopeia-National Formulary (USP-NF) Pharmacopeial Forum* volume 33(5).

Response: Comment incorporated.

Comment Summary #3: The commenter requests changing the *Residue on ignition* limit from “less than 1.5%” to “less than 5%” and revising the test conditions to be consistent with the Pullulan Monograph in Japan’s *Specifications and Standards for Food Additives, 8th Ed* (2007).

Response: Comment incorporated.