Commentary
Food Chemical Codex (FCC), Tenth Edition

March 1, 2016

In accordance with USP's provisionally-approved 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 on the Commentary section of the USP 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):

- Gluconic Acid
- Fully Hydrogenated Oils and Fats
- Monoammonium Glycyrrhizinate

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

- Aspartame
- Benzyl Disulfide
- Butyl Anthranilate
- Butyraldehyde
- Carbon, Activated
- Glucosamine Sulfate Potassium Chloride
- Glucosamine Sulfate Sodium Chloride
- Methyl 3-Nonenoate
- (z)-6-nonen-1-OL
- Polydextrose Solution
- D-Ribose

Monograph/Section: Gluconic Acid/Description
Expert Committee: Food Ingredients
No. of Comments: 1
Comment Summary #1: The commenter suggested specifying the type of stainless steel appropriate for this ingredient in the *Packaging and Storage section.*
Response: Comment not incorporated. This type of information is beyond the scope of the *FCC* monograph.
Expert Committee-initiated Change # 1: The last two sentences in the *Packaging and storage section* under *Description* describing various storage container types were deleted, because they were determined to be unnecessary and beyond the scope of the *FCC* monograph.

Monograph/Section: Fully Hydrogenated Oils and Fats/Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 3
Comment Summary #1: The commenter indicated that the use of the terms “lauric type” and “non-lauric type” in the *Acceptance criteria* for the *Identification A. Dropping Point* test was confusing and requested clarification.
Response: Comment not incorporated. The types “lauric” and “non-lauric” are now sufficiently defined in the *Description*.
Comment Summary #2: The commenter indicated that the column “part number” in footnote 5 is a model and not a part number. The commenter requested that this point

be clarified and that a second column be added based on the reference to AOCS Official Method Ce 1h-05.
Response: Comment incorporated.
Comment Summary #3: The commenter requested that the acronym "TAG" (triacylglycerol) be defined prior to use in the *Internal standard solution* described in the *Identification B. Fatty Acid Composition* test.
Response: Comment incorporated.
Comment Summary #4: The commenter suggested that a specific concentration be given for the *Standard solution* described in the *Identification B. Fatty Acid Composition* test.
Response: Comment not incorporated. Users should be able to determine the appropriate concentration based on the guidance provided in the monograph procedure.
Comment Summary #5: The commenter requested that the *Sample preparation* described in the *Identification B. Fatty Acid Composition* test be more specific, particularly in the first sentence and requested clarification.
Response: Comment not incorporated. Users should be able to determine the appropriate concentration based on the guidance provided in the monograph procedure.
Comment Summary #6: The commenter suggested deleting the note in the *Sample preparation* instructions in the *Identification B. Fatty Acid Composition Test* for the following reasons: (1) the peak for BHT commonly elutes before the peak for C14:0, which may cause the users to confuse the peaks; and (2) the note indicates that the addition of antioxidants may help protect highly unsaturated fatty acids from oxidation, but no significant amounts of highly unsaturated fatty acids should be present in this ingredient based on the way it is manufactured.
Response: Comment incorporated.
Comment Summary #7: The commenter suggested deleting the second sentence in the *System suitability* section of the *Identification B. Fatty Acid Composition* test, because some commercial fatty acid methyl ester mixtures which could be used to produce the *Standard solution* may not be sold with example chromatograms.
Response: Comment not incorporated. Users can purchase standard mixtures with reference chromatograms.
Comment Summary #8: The commenter indicated that the test and limit for *Iodine Value* may generally represent products with low levels of unsaturation, but stated that a test and limit for *trans* fatty acids should be added.
Response: Comment not incorporated. The Expert Committee will consider future revisions to the monograph upon the receipt of supporting data.
Expert Committee-initiated Change #1: In the *Identification B. Fatty Acid Composition* test, in the *Standard solution*, the following statement was added to clarify what type of standard is best suited for the analysis technique outlined in the monograph, "Note – Use USP FAME Standard Mixture RS or a mixture of methyl esters of pure fatty acids, in particular *cis*- and *trans*- isomers of octadecenoic (oleic), *trans*- isomers of octadecadienoic (linoleic) and octadecatrienoic (α- linolenic) acids with a reference chromatogram." .
Expert Committee-initiated Change #2: The reference to *Appendix VII* and the *Note* in the *Identification C. Iodine Value* test were deleted, because there was not sufficient

data supporting the use of the referenced titration method for samples exhibiting very low Iodine values. In addition, the following text was added:

> "Analysis: Using the chromatogram obtained in the *Identification* procedure *B – Fatty Acid Composition* test, calculate the iodine value as:
>
> Result = $\sum(P_X \times I_X)$
>
> P_X = percentage of unsaturated fatty acid X present in the Sample preparation (as the percent of total fatty acids)
> I_X = iodine conversion factor for the methyl ester of unsaturated fatty acid X, (triglyceride form, see Table 2)[2]
>
> Table 2: Iodine Value Conversion Factors

Unsaturated Fatty Acid (Shorthand Notation)	MW, Triglyceride	Moles of Iodine	MW Iodine	Factor (Triglyceride)
12:1	633.01	6	761.4270	1.2029
14:1	717.18	6	761.4270	1.0617
15:1 *trans*	759.16	6	761.4270	1.0030
15:1	759.16	6	761.4270	1.0030
16:1 *trans*	801.34	6	761.4270	0.9502
16:1	801.34	6	761.4270	0.9502
17:1 *trans*	843.42	6	761.4270	0.9028
17:1	843.42	6	761.4270	0.9028
18:1 *trans*	885.50	6	761.4270	0.8599
18:1	885.50	6	761.4270	0.8599
18:2 *trans*	879.50	12	1522.8540	1.7315
18:2	879.50	12	1522.8540	1.7315
18:2 CLA	879.50	12	1522.8540	1.7315
18:3 *trans*	873.50	18	2284.2810	2.6151
18:3	873.50	18	2284.2810	2.6151
20:1	969.66	6	762.4270	0.7853

> [Note: The iodine value is a measure of unsaturation and represents the number of grams of iodine absorbed, under the prescribed conditions, by 100 g of the test substance.]"

Monograph/Section: Monoammonium Glycyrrhizinate/Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 1
Comment Summary #1: The commenter requested lowering the limit for Lead in the section of *Inorganic Impurities*, because the Monoammonium Glycyrrhizinate products usually have Lead contents of NMT 1 mg/kg.

Response: Comment incorporated. The Lead specification was lowered from NMT 10 mg/kg to NMT 1 mg/kg based on the supporting data received.
Comment Summary #2: The commenter requested adding a CAS number to the monograph
Response: Comment incorporated.
Comment Summary #3: The commenter indicated that the formula weight of monoammonium glycyrrhizinate in the *FCC* monograph should be consistent with the one in the *USP–NF* monograph, which is 840.08.
Response: Comment incorporated.
Comment Summary #4: The commenter requested changing the phrase “on the anhydrous basis” to “on dried basis” in the *Acceptance criteria* for *Assay*, because the *FCC* monograph has specification of Loss on Drying.
Response: Comment incorporated.
Expert Committee-initiated Change #1: The synonym names, chemical structure, chemical formula, and formula weights were changed to be consistent with other compendial monographs for the same ingredient.