



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

February 28, 2015

In accordance with USP's Rules and Procedures of the 2010-2015 Council of Experts, 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 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 and Procedures of the Council of Experts. In cases when proposals advance to official status without republication in *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.

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Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCCF):

Monographs:

- Advantame
- Krill Oil
- Lithol Rubine BK

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

General Test and Assays:

- Enzyme Preparations Used in Food Processing
- Selenium Speciation
- Guidance Standard for UHPLC-MS/MS Screening of Nitrogen Containing Adulterants in Milk Ingredients

Monographs:

- (-)-Alpha-Bisabolol
- 1-Hexadecanol
- 2-Isobutyl-3 Methylpyrazine
- 2-Isobutyl-3-Methoxypyrazine
- Acesulfame Potassium
- Alginate-Konjac-Xanthan Polysaccharide Complex
- Benzoic Acid
- Beta-Carotene from Blakeslea Trispora
- BHT
- Butyl Laurate
- Calcium 5'-Guanylate
- Decyl Acetate
- Enzyme Preparations
- Ethylparaben
- Furfuryl Acetate
- Glucosamine Hydrochloride
- High Gamma-Linolenic Safflower Oil
- Lecithin
- Polydextrose
- Polyethylene Glycols
- Sodium Bisulfate
- Sodium Ferrous Citrate
- Sucrose
- Sulfur
- TBHQ
- Tea Polyphenols from Green Tea, Decaffeinated
- Xylose

Monograph/Section(s): Advantame/Multiple Sections
Expert Committee(s): Monographs—Food Ingredients
No. of Commenters: 1

Description

Comment Summary #1: The commenter requested deleting the specific manufacturing information included in the *Description* section, because most monographs for synthetic sweeteners do not include granular manufacturing details and these details are not helpful to users of the monograph.

Response: Comment incorporated.

Assay

Comment Summary #2: The commenter requested several changes to the Assay based on a newer technique which has been accepted by other compendia. The changes would require the use of five standard solutions for the creation of a standard curve. All of the standard solutions should contain benzoic acid as an internal standard, as should the sample solution. The peak areas of the reference standard should then be compared to those of benzoic acid for calculation of an average response factor for USP Advantame RS to the benzoic acid internal standard. The calculation of advantame content of the sample solution should, therefore, be determined based on the average response factor (from the USP Advantame Reference Standard) and the advantame and internal standard peak responses of the sample solution. Representative data and a validation report supporting these requested changes were submitted with the comments.

Response: Comment incorporated.

Specific Tests/Optical (Specific) Rotation

Comment Summary #3: The commenter requested that USP add the phrase “on the as-is basis (monohydrate)” after the optical rotation values in the *Acceptance criteria* to clarify that the test is to be performed on the as-is basis and not on a dried sample, nor using a sample weight corrected for water content.

Response: Comment incorporated.

Monograph/Section(s): Krill Oil/Multiple Sections
Expert Committee(s): Monographs—Food Ingredients
No. of Commenters: 2

Identification

Comment Summary #1: The commenter requested that the upper limit for linoleic acid (18:2, n-6) in the Identification test remain unchanged at 1.5 g /100g of oil. The commenter submitted a summary of data obtained from krill oil

batches produced over a four year period of time. 99.5% of the batches examined in that time period have a level of linoleic acid of NMT 1.4 g/100 g of oil.

Response: Comment not incorporated. Data from other manufacturers did support the limit proposed in the *FCC Forum* for linoleic acid (NMT 2.1 g/100 g oil); therefore, keeping the original limit of NMT 1.4 g/100 g would give an unfair advantage to a single manufacturer's product.

Specific Tests/Phospholipids

Comment Summary #2: The commenter requested that that the molecular weight of phosphatidylcholine included in the proposed revision (Table 3) be changed from 791 to 812, because this is a more commonly used molecular weight for phosphatidylcholine from krill oil in their experience.

Response: Comment not incorporated. Data submitted with the original revision proposal (relevant to products manufactured by multiple manufactures) supports the molecular weight value of 812. Sufficient contradictory data was not included in the comment.

Expert Committee Initiated Change #1: The Expert Committee changed the name of the fourth component listed in Table 3 to correct an error in the original revision proposal. The component with the approximate chemical shift (ppm, in reference to triphenyl phosphate) of -0.4 was changed from 1-Lysophosphatidylcholine to 2-Lysophosphatidylcholine to correct the typographical error.

Expert Committee Initiated Change #2: The Expert Committee changed two of the Calculations in the Phospholipids test in order to correct errors in the original revision proposal. In the calculation for mmolPL, the definition of mmolPL is changed from "millimoles of the phospholipid of interest in the Standard preparation (mmol)" to "millimoles of the phospholipid of interest in the Sample preparation (mmol)." Similarly, in the calculation for CPL, the definition of CPL is changed from "concentration of the phospholipid of interest in the Standard preparation (% w/w)" to "concentration of the phospholipid of interest in the Sample preparation (% w/w)" to correct the typographical errors.

Monograph/Section(s): Lithol Rubine BK/Organic Impurities,
Uncombined Intermediates and Products of
Side Reactions and Subsidiary Coloring
Matters

Expert Committee(s): Monographs—Food Ingredients

No. of Commenters: 1

Comment Summary #1: The commenter requested changing the conditions for preparing Standard Stock Solution B to "1 mg/mL USP Color Related Compound 005 RS in methanol." The commenter indicated that the originally proposed conditions of 5 mg/mL in methanol/water (1:1, v/v) did not fully dissolve USP Color Related Compound 005 RS.

Response: Comment incorporated.

Expert Committee Initiated Change #1: The Expert Committee added a note to the system suitability test to clarify the intended analysis conditions.