

COMMENTARY—*Food Chemicals Codex (FCC) Sixth Edition*
February 29, 2008

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.

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COMMENTARY—FCC Sixth Edition
MONOGRAPHS

Monograph/Section(s): Anethole/Specific Tests

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: The changes to this monograph were made as a result of the changes to Appendix XI that were adopted by the expert committee and are representative of the changes that were made to all flavor chemical monographs. The specific changes in this monograph are 1) the title of the requirement 'Angular Rotation' is changed to 'Optical (Specific) Rotation' to match the title of the method in Appendix IIB, 2) Appendix XIA has been eliminated and the text notes have been incorporated into the monographs, and 3) Appendix XIB is renamed Appendix XI.

Monograph/Section(s): L-Arginine Monohydrochloride/Identification

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: The identification test is changed to indicate that USP Arginine Hydrochloride RS is used to conduct the test.

Monograph/Section(s): Aspartame-Acesulfame Salt/Structure

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: The structure is revised to show the acid/base pair and clarify that the material is a combined salt as opposed to a physical mixture.

Monograph/Section(s): Benzyl Benzoate/Description, Specific Tests

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: The changes to this monograph were made as a result of the changes to Appendix XI that were adopted by the expert committee and are representative of the changes that were made to all flavor chemical monographs. The specific changes in this monograph are 1) The description of the odor is being changed from 'aromatic' to 'balsamic', 2) Appendix XIA has been eliminated and the text notes have been incorporated into the monographs, and 3) Appendix XIB is renamed Appendix XI.

Monograph/Section(s): Butane/Identification B

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: To conform to the new monograph format, the term "Sampling procedure" has been eliminated, the text has been moved to a [Note], and the pressure units have been converted to kPa and psi.

Monograph/Section(s): d-Camphor/Various

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: The changes to this monograph were made as a result of the changes to Appendix XI that were adopted by the expert committee and are representative of the changes that were made to all flavor chemical monographs. The specific changes in this monograph are 1) the name of the material is changed from D-Camphor to d-Camphor 2) the Identification test specifies the use of USP Camphor RS, 3) Appendix XIA has been eliminated and the text notes have been incorporated into the monographs, and 4) Appendix XIB is renamed Appendix XI.

Monograph/Section(s): Erythritol/Assay and Footnote

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary #1: The commenter suggested revising the footnote with the new contact information for obtaining the required USP Reference Standard.

Response: Comment incorporated.

Comment Summary #2: The commenter suggested changing the Sample solution in the Assay from '0.16 mg/ml' to '0.16 g/mL'.

Response: Comment not incorporated. The committee reverted back to using sample weight since it is used in the calculation.

Monograph/Section(s): Ethyl Acetate/Variou

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: The changes to this monograph were made as a result of the changes to Appendix XI that were adopted by the expert committee and are representative of the changes that were made to all flavor chemical monographs. The specific changes in this monograph are 1) the word 'fragrant' is deleted from the material description, 2) Appendix XIA has been eliminated and the text notes have been incorporated into the monographs, and 3) Appendix XIB is renamed Appendix XI.

Monograph/Section(s): Ethyl Cellulose/Residue on Ignition

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary: The commenter suggested changing the Residue on Ignition temperature from "800°C" to "600°C" to harmonize the FCC with USP/NF and Ph. Eur.

Response: Comment not incorporated. The commenter did not supply data to support a revision.

Monograph/Section(s): Ethyl Vanillin/Description and Specific tests

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: The changes to this monograph were made as a result of the changes to Appendix XI that were adopted by the expert committee and are representative of the changes that were made to all flavor chemical monographs. The specific changes in this monograph are 1) the phrase 'affected by strong light' is deleted from the material description, 2) Appendix XIA has been eliminated and the text notes have been incorporated into the monographs, and 3) Appendix XIB is renamed Appendix XI.

Monograph/Section(s): Glycerol Ester of Gum Rosin/Variou

Expert Committee(s): FIEC

No. of Commenters: 2

Comment Summary #1: The commenter suggested eliminating the current USDA N color specification and references to ASTM method D509 referencing only the Gardner color specification 9 in the Description.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Comment Summary #2: The commenter suggested adding the synonym "ester gum" following the Title.

Response: Comment incorporated.

Comment Summary #3: Commenter requested that the current sentence under Description be replaced with the sentence "When intended for use in chewing gum base, the product is usually purified by steam stripping, but when intended for use in adjusting the density of citrus oils for beverages, it is purified by countercurrent steam distillation."

Response: Comment incorporated.

Comment Summary #4: The commenter suggested adding "beverage stabilizer" under Function.

Response: Comment incorporated.

Monograph/Section(s): Glycerol Ester of Partially Dimerized Rosin/Description

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary: The commenter suggested eliminating the USDA color specification and references to ASTM method D509 referencing only the Gardner color specification in the Description.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Monograph/Section(s): Glycerol Ester of Partially Hydrogenated Gum Rosin/Description; Drop Softening Point

Expert Committee(s): FIEC

No. of Commenters: 3

Comment Summary #1: The commenter suggested eliminating the USDA color N specification and references to ASTM method D509 referencing only the Gardner color specification 9 in the Description.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Comment Summary #2: Two commenters suggested changing the Acceptance Criteria for the proposed Ring and Ball Softening Point procedure from “79°C or higher” to “74°C or higher” or to “68°C or higher.”

Response: Comments not incorporated. The commenters did not supply sufficient data to support either revision.

Monograph/Section(s): Glycerol Ester of Partially Hydrogenated Wood Rosin/Description

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary: The commenter suggested eliminating the USDA N color specification and references to ASTM method D509 referencing only the Gardner color specification 9 in the Description.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Monograph/Section(s): Glycerol Ester of Polymerized Rosin/ Ring-and-Ball Softening Point

Expert Committee(s): FIEC

No. of Commenters: 2

Comment Summary: Commenter suggests that the 90°C proposal for the Ring-and-Ball Softening Point be changed to 100°C based on supporting Product data sheets.

Response: Comment not incorporated at this time. The expert committee believes that more data is necessary to support the changes to the Ring-and-Ball Softening Point procedure.

Monograph/Section(s): Glycerol Ester of Tall Oil Rosin/Description

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary: The commenter suggested eliminating the USDA color specification and references to ASTM method D509 referencing only the Gardner color specification in the Description.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Monograph/Section(s): Glycerol Ester of Wood Rosin/Description

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary: The commenter suggested eliminating the USDA N color specification and references to ASTM method D509 referencing only the Gardner color specification 9 in the Description.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Monograph/Section(s): Isobutane/Identification B

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: To conform to the new monograph format, the term "Sampling procedure" has been eliminated and the text has been moved to a note [Note].

Monograph/Section(s): Pentaerythritol Ester of Wood Rosin/Description

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary: The commenter suggested eliminating the USDA color specification and references to ASTM method D509 referencing only the Gardner color specification in the Description. The commenter suggested changing the Gardner color specification from 10 to 11 to be consistent with established specifications, process capability and the correlation between USDA and Gardner color.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Monograph/Section(s): Pentaerythritol Ester of Partially Hydrogenated Wood Rosin/Description

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary: The commenter suggested eliminating the USDA color specification and references to ASTM method D509 referencing only the Gardner color specification in the Description.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Monograph/Section(s): Petrolatum/Various Sections

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary #1: Commenter suggested deleting the text in the Description statement that Petrolatum is “partially soluble in ether”.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Comment Summary #2: Commenter suggested changing the Consistency test to align with ASTM D937.

Response: Comment incorporated. For future revisions of this monograph, committee are seeking public input for the addition of a penetrometer cone designation for the Consistency test which corresponds to dimensions given in the monograph, if such a designation exists.

Comment Summary #3: Commenter suggests changing the acceptance criterion for the Melting range test from “between 38° and 60°C” to “between 35°C - 70°C” to be consistent with the European Pharmacopoeia monograph for White Soft Paraffin.

Response: Comment not incorporated. The commenter did not supply sufficient data to support the revision.

Monograph/Section(s): Petroleum Wax/Title

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary: Commenter request that 7 additional CAS-numbers be listed in the title of the monograph: 92045-76-6, 97862-95-8, 64742-42-3, 85029-72-7, 64742-43-4, 92045-75-5, 97862-91-4.

Response: Comment not incorporated. The committee will not include additional CAS-numbers until it has verified the CAS-numbers that represent items in commerce today. All CAS numbers that correspond to items in commerce will be included in future monograph updates.

Monograph/Section(s): Polyvinyl alcohol/water-insoluble substances, viscosity

Expert Committee(s): FIEC

No. of Commenters: 1

Comment Summary #1: Commenter suggests adding clarifying instructions to the sample solution preparation to the Water-insoluble Substances test as follows "Treat sample with 100 mL of hot water and stir for an additional one hour as the sample temperature decreases. Then filter through a tared 100-mesh screen".

Response: Comment incorporated.

Comment Summary #2: Commenter requests the deletion of the sentence “Filter the mixture through a tared 100-mesh screen into a 250-mL conical flask” from the viscosity test because it is redundant.

Response: Comment incorporated.

COMMENTARY—FCC Sixth Edition General Tests and Assays

Monograph/Section(s): Invertase Assay, Appendix V/Reagents & Solutions

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change: Molecular Weights (MW's) are removed from Reagents and Solutions section.

Monograph/Section(s): Appendix IIIC Spectrophotometric Identification Tests

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Change #1: Appendix IIIC was developed by combining three tests. The Infrared absorption and Ultraviolet absorption tests came from the USP-NF and the third tests came from Section 4 of FCC V Infrared Spectra. The Food Ingredients Expert committee felt it was appropriate to re-word and move text to improve clarity for the FCC user.

Expert Committee-initiated Change #2: Infrared Spectra added a statement clarifying what this test is used for and distinguishing it from the preceding Infrared Absorption test.

Expert Committee-initiated Change #3: The preparation techniques have been converted into tabular format for the Infrared absorption test.

Expert Committee-initiated Change #4: The Expert Committee felt that the section from USP-NF text on polymorphs was inappropriate for FCC and removed this text.

Expert Committee-initiated Change #5: The Ultraviolet Absorption test added a sentence to clarify what this test is used for and to distinguish it from the preceding tests. The <U> reference has been deleted since there is only one UV test included in FCC.

Monograph/Section(s): APPENDIX XI: FLAVOR CHEMICALS (OTHER THAN ESSENTIAL OILS)/APPENDIX XI A, B, and C

Expert Committee(s): FIEC

No. of Commenters: 0

Expert Committee-initiated Changes: The Expert Committee 1) eliminated the entire XIA section from this appendix, 2) moved corresponding test method cross-references and condition information directly into monographs 3) moved any corresponding necessary information into the General Provisions.

Specifications: Since flavor chemicals are no longer separated from the other FCC monographs it is appropriate to include the nomenclature for these materials in the General Provisions, as opposed to in a separate Appendix.

Notes 1 & 2: since flavor chemicals are no longer separated from the other FCC monographs it is more appropriate to include these Notes in the General Provisions as opposed to in a separate Appendix.

Note 3, Boiling Point: monographs for flavor chemicals are now qualified with the tilde (~) symbol to indicate that they are approximate values. The ~ symbol was also added to General Provisions sections "Description" and "...Abbreviations" to clarify this point.

Note 4, Solubility in Alcohol: Flavor chemical monographs now direct user to Appendix VI. Temperature is not necessary as this appendix tells user to measure at 25°.

Note 5, Identification: Flavor chemical monographs now direct user to Appendix IIIC, Spectrophotometric Identification Tests and include the acceptance criteria.

Note 6, Assay: Flavor chemical monographs now direct user to Appendix XI test methods. Monographs now qualify the acceptance criterion value with NLT, eliminating the need to clarify that "assay requirements are specified as minimum values"

Note 7, Acid Value: Monograph now directs user to the appropriate appendix method. M-15 test specifies use of phenolphthalein TS as the indicator, making this statement unnecessary.

Note 8, Refractive Index: Monographs now direct user to Appendix II, and specify the appropriate temperature to use.

Note 9, Specific Gravity: Monographs now direct user to “determine by any reliable method (See General Provisions)”, and specify the appropriate temperature to use.

Note 10, Other Requirements: Monographs now qualify the numerical limits with the appropriate terms such as NLT or NMT. Since monographs now directly reference the appropriate appendix, the second sentence is no longer necessary.

Appendix XI: The Food Ingredients Expert committee feels that Appendix XIB, Test Methods for Flavor Chemicals, method M-1a/b (Assay by GC) as proposed in June FCC Forum unnecessarily cross-references Appendix XIC (GC Assay of Flavor Chemicals) and moves the entire text in XI C directly into M-1a/b. The Committee feels it is more convenient for user to include Appendix XIC text directly in the M-1a/b method. These changes leave only section remaining in the Appendix XI so the suffixes A, B and C will be eliminated from Appendix XI.

Table on page 3, under M-3: some incorrect equivalent weights in table for M-3a have been corrected as follows:

levulinic acid = 58.06

2-methyl butyric acid = 51.07

4-methyl pentanoic acid = 58.08

2-methyl pentanoic acid = 58.08