

COMMENTARY – *Food Chemicals Codex (FCC) 6 Second Supplement*

Revision proposals published in *Food Chemicals Codex (FCC) Forum* often elicit public comments that are forwarded to the Food Ingredients Expert Committee (FIEC) 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 FIEC'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 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.

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:

Polyvinyl Acetate

No comment received for the following proposals:

General Tests and Assays

Appendix II -- Physical Tests and Determinations
Appendix III -- Chemical Tests and Determinations
Appendix V -- Enzyme Assays

Monographs

Alpha-Cyclodextrin	Potassium Metabisulfite
Ammonium Citrate, Tribasic	Potassium Sulfate
Sodium Fumarate	Potassium Sulfite
Sorbitan Monooleate	Sodium Bisulfate
Stearyl Citrate	Sodium Bisulfite
Synthetic Iron Oxide	Sodium Metabisulfite
Thaumatococcus	Sucralose
Magnesium Phosphate, Tribasic	Tannic Acid
Nickel	

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Monograph/Section(s): Calcium Propionate/Assay

Expert Committee(s): Food Ingredients

No. of Commenters: 0

Expert Committee Initiated Change #1: The FIEC added a step to the Assay procedure to remove water insoluble calcium compounds by filtration before titration to improve the selectivity of the procedure for calcium propionate and to thereby prevent potential adulteration of this ingredient with water insoluble calcium containing compounds which would artificially inflate the Assay result.

Monograph/Section(s): Rebaudioside A/Multiple

Expert Committee(s): Food Ingredients

No. of Commenters: 12

Comment Summary #1: The commenter suggested harmonizing the FCC monograph with the Steviol Glycosides monograph in the Compendium of Food Additive Specification published by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Response: Comment not incorporated. The FIEC encourages the submission of data to support the proposal of separate FCC monographs for stevia based ingredients including those intended as a mixture of steviol glycosides, and those intended as individual high purity steviol glycosides.

Comment Summary #2: The commenter suggested changing the *Title* of the monograph from “Rebaudioside A” to “Reb A”.

Response: Comment not incorporated. There was no information submitted to justify that “Reb A” is a more established common or usual name than “Rebaudioside A”

Comment Summary #3: The commenter suggested the addition of “Reb A” to the list of synonym names because it is being used in the marketplace to identify this ingredient and would be useful to include as a synonym name.

Response: Comment incorporated

Comment Summary #4: The commenter suggested the removal of “Rebiana” from the list of synonym names because it is not an established common or usual name for this ingredient.

Response: Comment not incorporated. Information was submitted indicating that “Rebiana” is being used in the marketplace to identify this ingredient and would be useful to include as a synonym name.

Comment Summary #5: The commenter suggested adding the IUPAC chemical name to the *Chemical information* section since IUPAC names are commonly used.

Response: Comment incorporated.

Comment Summary #6: The commenter suggested adding of the term “granule” to physicochemical descriptors used in the *Description* section to be inclusive of the description of the ingredient in GRAS Notice No. GRN 000252.

Response: Comment incorporated

Comment Summary #7: The commenter suggested revising the solubility information listed in the *Description* section from “It is freely soluble in water and sparingly soluble in ethanol” to “It is freely soluble in ethanol:water 50/50 (v/v), sparingly soluble in water,

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and sparingly soluble in ethanol”. This suggestion was supported by data and the solubility definitions in the FCC General Provisions.

Response: Comment incorporated.

Comment Summary #8: The commenter suggested changing the technical effect, “Nonnutritive sweetener” listed in the *Function* section to “Sweetener” for consistency with the Steviol Glycosides monograph in the Compendium of Food Additive Specification published by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and GRAS Notice No. GRN 000252.

Response: Comment not incorporated. The term “Non-nutritive sweetener” is consistent with that used to describe other ingredients in FCC with the same technical effect such as Sucralose.

Comment Summary #9: The commenter suggested replacing the proposed Assay and *Related Steviol Glycosides* test procedures with that used in the Steviol Glycosides monograph in the Compendium of Food Additive Specification published by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Response: Comment not incorporated. Performance characteristics data was not supplied to justify use of the JECFA method instead of proposed FCC method.

Comment Summary #10: The commenter suggested replacing the proposed Assay and *Related Steviol Glycosides* test procedures with the ones used in GRAS Notice No. GRN 000252.

Response: Comment not incorporated. Performance characteristics data was not supplied to justify use of the GRAS Notice No. GRN 000252 method instead of the proposed FCC method.

Comment Summary #11: The commenter suggested removing the “Approx. Capacity Factor (*k'*)” column from *Table 1* because this information is not used in the monograph.

Response: Comment incorporated

Comment Summary #12: The commenter suggested changing the “NLT 97.0% and NMT 102.0%” acceptance criteria for the Assay to “NMT 95%” to be inclusive of food-grade rebaudioside A materials represented in the GRAS Notice No. GRN 000252 which received a “No Questions” letter from the US FDA. The commenter also provided supporting batch data.

Response: Comment incorporated

Comment Summary #13: The commenter suggested replacing the “NMT 3.0%” acceptance criteria for *Related Steviol Glycosides* with a “NMT 5%” limit to be inclusion of those ingredients in commerce meeting GRAS Notice No. GRN 000252 specifications. The commenter also provided supporting batch data.

Response: Comment incorporated.

Comment Summary #14: The commenter suggested changing the sample solution concentration used for the *pH* test procedure from “10 mg/mL” to “1 in 100 solution”

Response: Comment not incorporated because these two expressions represent the same concentration and the preferred FCC format for concentrations is mg/mL in this case.

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Expert Committee Initiated Change #1: The FIEC removed the “9CI” designation at the end of the inverted CAS chemical name listed in the *Chemical information* section since this reference to the 9th Cumulative Index of Chemical Abstracts was not useful to monograph users.

Expert Committee Initiated Change #2: The FIEC expanded the method of manufacturer information in the *Description section* to reflect the general principles of the manufacturing process used for all known high purity rebaudioside A materials which are currently approved for use in foods.

Expert Committee Initiated Change #3: The FIEC added a *Note* to the beginning of the monograph to indicate the hygroscopic nature of the ingredient and to emphasize the need for appropriate handling in test procedures.

Expert Committee Initiated Change #4: The FIEC changed the volumetric addition of acid used in the *Acetate buffer* preparation in the *Assay* to a pH adjustment step with acid for user simplicity.

Expert Committee Initiated Change #5: The FIEC revised the *Note* listed in the *Acetate buffer* preparation of the *Assay* to clarify the expected effect of changing the pH of this solution.

Expert Committee Initiated Change #6: The FIEC revised the *Note* listed in the *Mobile phase* preparation of the *Assay* to use the retention time for rebaudioside A instead of rebaudioside B because the peak for rebaudioside A can be identified using the *Rebaudioside A standard solution*.

Expert Committee Initiated Change #7: The FIEC revised the *Retention Time* criterion listed in the *Suitability requirements* of the *Assay* to be based on the retention time for rebaudioside A instead of rebaudioside B because the peak for rebaudioside A can be identified using the *Rebaudioside A standard solution*.

Expert Committee Initiated Change #8: The FIEC revised the *Arsenic* test to include an additional suitable test procedure, the colorimetric FCC General Test Procedure for Arsenic.

Expert Committee Initiated Change #9: The FIEC revised the *Lead* test to include an additional suitable test procedure, the graphite furnace atomic absorption General FCC method.

Expert Committee Initiated Change #10: The FIEC removed the *Loss on Drying* test procedure and acceptance criterion because it provides redundant information on the water content of the ingredient and is not as accurate for this purpose compared to the Karl Fischer-based method for water determination.

Expert Committee Initiated Change #11: The FIEC removed the *Optical (Specific) Rotation* test procedure and acceptance criterion because they did not receive data that justifies the necessity of this specification. The FIEC encourages the submission of data in the future that demonstrate the usefulness of this test procedure and acceptance criteria in substantiating the identity of an ingredient that is a mixture of optically active constituents.