

codex alimentarius commission

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Agenda Item 10 (c)

CX/FA 09/41/15 Add.1

February 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-first Session

Shanghai, China, 16-20 March 2009

COMMENTS ON DISCUSSION PAPER ON INCONSISTENCIES IN THE NAMES OF COMPOUNDS IN THE CODEX SPECIFICATIONS FOR IDENTITY AND PURITY OF FOOD ADDITIVES AND IN THE INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES

The following comments have been received from the following Codex members and observers:

Brazil, European Community, Democratic People's Republic of Korea, CEFIC, ELC, IFAC

Brazil

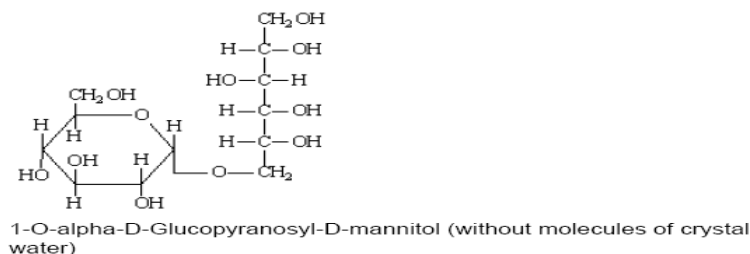
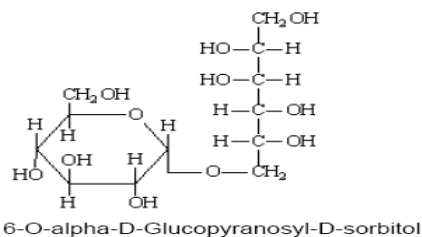
Isomaltitol should be excluded from the INS list as synonym for isomalt, because they are not the same compound.

As shown below, isomalt is a mixture of isomaltitol (alpha-D-glucopyranosido-1,6-sorbitol (GPS)) and alpha-D-glucopyranosido-1,6-mannitol (GPM).

JECFA Specification (2008) clearly describes isomalt (CAS number 64519-82-0) is described as a mixture not as a single substance and did not consider isomaltitol (534-73-6) as a synonym.

SYNONYMS	Hydrogenated isomaltulose; INS No. 953
DEFINITION	A mixture of hydrogenated mono- and disaccharides whose principal components are the disaccharides:
Chemical names	6-O-alpha-D-Glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O-alpha-D-Glucopyranosyl-D-mannitol dihydrate (1,1-GPM)
C.A.S. number	64519-82-0
Chemical formula	6-O-alpha-D-Glucopyranosyl-D-sorbitol: $C_{12}H_{24}O_{11}$ 1-O-alpha-D-Glucopyranosyl-D-mannitol dihydrate: $C_{12}H_{24}O_{11} \cdot 2H_2O$

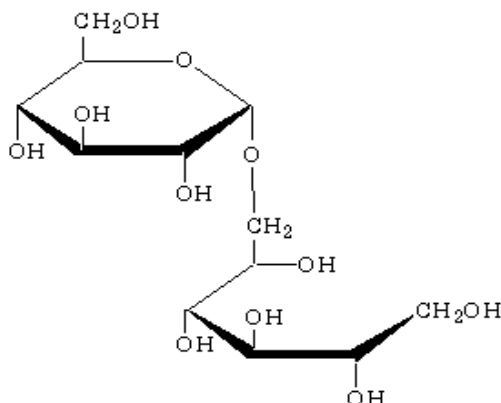
Structural formula



Formula weight

6-O-alpha-D-Glucopyranosyl-D-sorbitol: 344.32

1-O-alpha-D-Glucopyranosyl-D-mannitol dihydrate: 380.32

ISOMALTITOL*O*-α-D-Glucopyranosyl-(1→6)-D-glucitolFormula: C₁₂H₂₄O₁₁

Molecular Weight: 344.32

<http://www.seikaken-material.jp/hbl/product-spec/ih121.html>

Comments to inconsistencies to which no action decision was assigned.

Considering the short time for the discussion taken at the 40th CCFA, the expression “no action” was maintained in the document to some food additives, although there was no discussion about it. Brazil had comments on this issue during the last Session and would like to reinforce them.

For consistency with other names and recommendations, Brazil suggests including the synonym “caustic caramel” to **INS 150a** in the INS list.

For consistency with the recently adopted name for **INS 160a(ii)** in the INS system – Carotenes, beta-(vegetable), JECFA should be asked to include this synonym in the specification.

Since only the synthetic magnesium silicate was evaluated by JECFA, Brazil suggests including “(synthetic)” in the name of **INS 553(i)** to clearly differentiate from natural magnesium silicate.

European Community

The European Community and its Member States (ECMS) would like to thank the Danish delegation for the draft discussion paper on inconsistencies in the names of compounds in the Codex specifications for identity and purity of food additives and in the INS list.

In section 4, the ECMS suggest to revisit the allocation of “Isomaltitol” as a synonym of Isomalt (INS 953) in the International Numbering System. Indeed, Isomalt is a mixture of the two isomers 1,6-GPS (CAS 534-73-6) and 1,1-GPM (CAS 20942-99-8) while Isomaltitol describes only the 1,6-GPS part of isomalt.

Therefore the ECMS suggest that “Isomaltitol” should be deleted. Instead, the term “hydrogenated isomaltulose” should be preferred as a synonym of Isomalt.

Democratic People’s Republic of Korea

1. Sodium Sulfate (INS no.514)

Discussion Paper noted that INS no.514 covers two Sodium Sulfates, but in fact, it covers three Sodium Sulfates :

- Na_2SO_4 (Anhydrous);
- $\text{Na}_2\text{SO}_4 \cdot 10\text{H}_2\text{O}$ (Decahydrate);
- Sodium Hydrogen Sulfate(68th JECFA).

Therefore, we suggest that CCFA should consider that either substance name of INS no. 514 would be taken the plural form for these three substances, or Codex Specifications would include them individually.

2. Potassium Sulfate (INS no. 515)

Discussion Paper noted that Potassium Sulfate covers two Potassium Sulfates used as food additives: Potassium Sulfate and Potassium Hydrogen Sulfate.

But Codex Specifications and JECFA Specifications include the only Potassium Sulfate.

We suggest that CCFA should investigate whether Potassium Hydrogen Sulfate is used as a food additive.

If so, Potassium Sulfate and Potassium Hydrogen Sulfate should be listed individually. If not, it should be taken the singular form in INS list.

3. Fumarates (INS no. 365, 366, 367)

- In the case of INS no. 365 Sodium Fumarate in Codex Specifications, the only Sodium Hydrogen Fumarate is used as a food additive.

Therefore, we suggest that INS list should use the singular form.

- In the case of INS no. 366 Potassium Fumarate, the only Dipotassium Fumarate, $\text{C}_4\text{H}_2\text{K}_2\text{O}_4$, is used as a food additive.

We suggest that INS list should use the singular form, i.e., “Potassium Fumarate”.

- In the case of INS no. 367 Calcium Fumarate, the only Calcium Fumarate, $\text{C}_4\text{H}_2\text{CaO}_4$, is used as a food additive.

Therefore, we suggest that INS list should use the singular form, i.e., “Calcium Fumarate”.

4. Aluminium Sulfate (INS no. 520)

In the case of INS no. 520 Aluminium Sulfate, “anhydrous” should be withdrawn in the Codex Specifications because Aluminium Sulfates with the different number of crystal water are used as food additives.

We support the discussion paper with the respect of other problems excepting the above.

CEFIC (The European Chemical Industry Council)

The European Chemical Industry Council (CEFIC) represents European-based and globally active manufacturers of chemicals of which a considerable number are also used in or with food. On behalf of the CEFIC Food Regulatory Panel and the European Citric Acid Manufacturers Association (ECAMA) comments and proposals are submitted in response to CX/FA 09/41/15 concerning the “discussion paper on inconsistencies in the names of compounds in the Codex specifications for identity and purity of food additives and in the international numbering system for food additives”.

Cefic Comments and proposals to point 5 and 6:

1. Comments to point 5: JECFA to reconsider names:

- Substance INS 101 (i) riboflavin, synthetic:
 - Cefic is surprised that the Codex Alimentarius Committee for Food Additives and JECFA consider a differentiation between synthetic riboflavin and riboflavin obtained from fermentation of *B. subtilis*.
 - Such consideration does not take into consideration that for many years riboflavin obtained by fermentation of other microorganisms has been available on the market in many countries. This riboflavin conforms to the riboflavin specifications applicable for material from all sources not specifically addressed. Until riboflavin from *B. subtilis* no differentiation between material between the different sources was made, and statements on synthetic origin of riboflavin as the alternative to riboflavin obtained from *B. subtilis* seem to have been introduced arbitrarily and without respect to the available material conforming to evaluations and specifications at the time riboflavin from *B. subtilis* was evaluated.

Proposal:

Cefic proposes to address specifications in the following way:

- Riboflavin (i): Riboflavin in general without further specification
- Riboflavin (ii): Riboflavin from *B. subtilis*

2. Proposal to point 6: CCFA to ask JECFA for advice:

- Cefic recommends to use the following names for the calcium citrates:
 - 333i monocalcium citrate
 - 333ii dicalcium citrate
 - 333iii tricalcium citrate
- The recommendation for the sodium citrates are as follows:
 - 331i monosodium citrate
 - 331ii disodium citrate
 - 331iii trisodium citrate
- The recommendation for the potassium citrates are as follows:

(There is no dipotassium citrate on the market)

 - 332i monopotassium citrate
 - 332ii tripotassium citrate

ELC (Federation of European Food Additives, Food Enzymes and Food Cultures Industries)

With reference to CX/FA 09/41/15, ELC would draw your attention to the fact that “isomaltitol” is an incorrect synonym for isomalt, and therefore we strongly recommend that JECFA should not be asked to consider including “isomaltitol” as a synonym of isomalt in the specifications.

With reference to our comments submitted by e-mail dated 4 December 2008, we would like to provide further justification to our recommendation that JECFA should not be asked to consider including “isomaltitol” as a synonym of isomalt (INS No 953) in the specifications.

In addition, we would draw your attention that the term "isomaltitol" was mistakenly introduced when creating the GSFA. JECFA does not provide a basis for this and we see the need to delete the term "isomaltitol" from the GSFA. "Isomalt" and "hydrogenated isomaltulose" are the correct terms.

Background, rationale and evidence are given in the following:

(1) Current issue: CX/FA 09/41/15 Discussion paper on inconsistencies in the names

Isomalt is a generic name assigned by the British Pharmacopoeia Commission in 1977. Isomalt (CAS 64519-82-0) is a mixture of the two isomers 1,6-GPS (CAS 534-73-6) and 1,1-GPM (CAS 20942-99-8).

“Isomaltitol” (or in German “isomaltit) describes only the 1,6-GPS part of isomalt and is another chemical entity. Thus it is evident that “isomaltitol” can not be used as a synonym for “isomalt” (Reference 2: Expert opinion of 1996 that has been submitted for the 46th JECFA meeting.

We therefore kindly ask **not re-including “isomaltitol”** as a synonym for isomalt in the specification. The specification on isomalt as prepared at the 69th JECFA (2008), published in FAO JECFA Monographs 5 (2008), **is correct** (Reference 3).

Instead, we apply for **deletion of “isomaltitol”** in the GSFA where it is erroneously used as a synonym for isomalt.

The synonym that should remain and used for “isomalt” is “hydrogenated isomaltulose”.

The reasons for this proposal are in the following detailed under “History of isomalt JECFA evaluations”, describing the mix-up of the terms “isomaltitol” as synonym for “isomalt” over years.

(3) History of isomalt JECFA evaluations regarding the synonym “isomaltitol”

➤ “Isomalt” was initially evaluated by JECFA in 1981; at that time, “isomalt” was improperly named “isomaltitol” (in German: “isomaltit”)

→ Reference 4: 25th JECFA Report, *sweetening agents, point 3.3.*

➤ In a subsequent JECFA evaluation in 1986, “isomaltitol” was correctly replaced by “isomalt”. This replacement was done due to the fact that “isomalt” is the generic name for the mixture of GPM and GPS (CAS 64519-82-0), whereas “isomaltitol” describes the GPS part only (CAS 534-73-6). Consequently, “isomaltitol” cannot be used as a synonym for “isomalt”.

→ Reference 5: 29th JECFA Report

➤ For unknown reasons, “isomaltitol” was re-included as a synonym for “isomalt” in a later revision of the specification in 1992

→ Reference 6: 39th JECFA Report

→ Reference 7: FNP 52, Add. 1

➤ In order to remove the incorrect synonym, we supplied an “Expert opinion on the generic name of isomalt” by Prof. Lichtenthaler, Technical University of Darmstadt, Germany to JECFA. This letter was sent together with a subsequent request for revision of the isomalt specification in 1996.

→ Reference 2: Letter to Dr. Paakkanen, JECFA, January 12, 1996

➤ Following the subsequent 46th JECFA session in 1996, “isomaltitol” was correctly removed as a synonym:

→ Reference 8: 46th JECFA Report

→ Reference 9: FNP 52, Add. 4, 1996

From this history it is evident, that the use of “isomaltitol” and “isomaltit” as a synonym for “isomalt” is not correct and requires elimination wherever used to avoid further confusion.

In our view the term “isomaltitol” was incorrectly introduced when creating the GSFA. JECFA does not provide a basis for this and we see the need to remove the term “isomaltitol” from the GSFA. “Isomalt” and “hydrogenated isomaltulose” are the correct terms.

We hope that this matter can finally be solved in the upcoming Codex meeting on Food Additives at 16-20 March in Shanghai, China.

As indicated above we want to address the mistakenly reference to “isomaltitol” as a synonym for isomalt in GSFA online, that is strongly recommended to be deleted:

(4) GSFA Online (Reference 10) - Synonyms used for “isomalt”

In GSFA Online, under isomalt INS no. 953, the listing appears as follows:

<u>INS no.</u>	<u>Food Additive or Group</u>
953	Hydrogenated isomaltulose*
953	Isomalt (<i>isomaltitol</i>)
953	<i>Isomaltitol*</i>

Additives marked with an asterisk (“*”) indicate synonyms for official names.

Our proposal for amendment of GSFA Online is as follows:

953	Hydrogenated isomaltulose*
953	Isomalt (Hydrogenated isomaltulose)

We appreciate this opportunity to present our comments on the topic of the inconsistency in the synonyms used for the Food Additive isomalt (INS 953) and the attention they will receive.

The References of ELC comments

Can be provided upon request:

- (1) Discussion paper on inconsistencies in the names of compounds in the Codex Specifications for Identity and Purity of Food Additives and in the International Numbering System for Food Additives (Agenda Item 10 (c), CX/FA 09/41/15, November 2008 ftp://ftp.fao.org/codex/ccfa41/fa41_15e.pdf)
- (2) Südzucker letter to Dr. Paakkanen, JECFA Rome, January 12, 1996, including expert opinion on the generic name of isomalt by Prof. Lichtenthaler, Technical University of Darmstadt, Germany
- (3) Current isomalt specification <http://www.fao.org/ag/agn/jecfa-additives/specs/monograph5/additive-241-m5.pdf>
- (4) 25th Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report Series 669, Geneva 1981, http://whqlibdoc.who.int/trs/WHO_TRS_669.pdf
- (5) 29th Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report Series 733, Geneva 1986, http://whqlibdoc.who.int/trs/WHO_TRS_733.pdf
- (6) 39th Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report Series 828, Geneva 1992; http://whqlibdoc.who.int/trs/WHO_TRS_828.pdf
- (7) Compendium of food additive specifications, FAO Food and Nutrition Paper 52, Addendum 1
- (8) 46th Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report Series 868, Geneva 1997; http://whqlibdoc.who.int/trs/WHO_TRS_868.pdf
- (9) Compendium of food additive specifications, FAO Food and Nutrition Paper 52, Addendum 4
- (10) GSFA Online <http://www.codexalimentarius.net/gsaonline/additives/index.html#I>
- (11) GSFA Online <http://www.codexalimentarius.net/gsaonline/additives/index.html#I>

IFAC (The International Food Additives Council)

The International Food Additives Council (IFAC) is an international association representing companies that produce high quality substances used worldwide as food additives. IFAC, which holds Non-Government Organization status before Codex Alimentarius, is pleased to submit the following comments in response to CX/FA 09/41/15:

IFAC agrees with the proposal as written in CX/FA 09/41/15 for INS 140, chlorophyll, that CCFA should consider changing the name in the INS to “chlorophylls.”

IFAC agrees with the proposal as written in CX/FA 09/41/15 to consider changing names in the INS for the phosphates listed (INS number 335, 338, 339, 340, 341, 342, 343, and 350). IFAC supports the recommendation to delete “ortho” from the names in the INS and that the CCFA should consider using the specification name for the individual salts.

IFAC agrees with the proposal as written in CX/FA 09/41/15 to consider changing names in the INS for carrageenan (INS 407) and the recommendation to CCFA to consider deleting the superfluous text in the INS name.

IFAC also agrees with the proposal as written in CX/FA 09/41/15 for INS 445, glycerol ester of wood rosin and agrees with the recommendation for CCFA to consider changing the name in the INS list to glycerol ester of wood rosin.

IFAC agrees with the proposal as written in CX/FA 09/41/15 for INS 1200, Polydextrose, that CCFA consider using the specification name as the INS name, by deleting the “A” and “N.”

IFAC recommends that for INS 904, the name should be “Shellac, bleached” in the INS. IFAC believes that bleached and unbleached Shellac should not be listed individually in the INS.

IFAC disagrees with the proposal as written in for INS 953, isomalt that JECFA should be asked to consider including isomaltitol as a synonym in the specifications for isomalt. These names are not synonyms, as "Isomaltitol" describes only one part of "Isomalt." Therefore, there should not be a recommendation JECFA that isomaltitol be added as a synonym for isomalt.

IFAC disagrees with the proposal as written for INS 101(i), Riboflavin, that JECFA should change the title of the specification to "Riboflavin, synthetic." IFAC recommends that INS 101(i) be listed as "Riboflavin." Official specifications and regulations in the Food and Drug Administration's Code of Federal Regulations, the Joint Expert Committee on Food Additives (JECFA) and the EU Directive for Colours (E101(i)) all use the title "riboflavin." We recommend that CCFA also do so for consistency.

Lastly, IFAC agrees with the proposal as written for INS 450 that JECFA should be asked to consider using diphosphate for all substances under INS 450 in order to be consistent. IFAC also agrees with the proposal as written for INS 452 that JECFA should be asked to reconsider the naming of polyphosphates in a consistent manner.