

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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CX 5/20

CL 2004/21-NFSDU  
May 2004

**TO:** Codex Contact Points  
Interested International Organizations

**FROM:** Secretary, Codex Alimentarius Commission  
Joint FAO/WHO Food Standards Programme  
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

**SUBJECT:** **ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN  
COMPOUNDS FOR THE USE IN FOODS FOR INFANTS AND  
CHILDREN (CAC/GL 10-1979 (amended 1983, 1991))**

**DEADLINE:** **31 August 2004**

**COMMENTS:**

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## BACKGROUND

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is revising the Advisory List(s) of Mineral Salts and Vitamin Compounds for the Use in Foods for Infants and Young Children. The last 25<sup>th</sup> Session of the Committee requested the Delegation of Germany to revise the list on the basis of written comments and comments at the current session with the understanding that the revised list would be circulated at Step 3 (para. 137 of ALINORM 04/27/26).

Governments and international organizations are invited to submit their comments on the above subject matter (see Appendix) at Step 3 of the Codex Procedure and should do so in writing preferably by email to the above addresses **before 31 August 2004**.

**Appendix****ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN COMPOUNDS  
FOR THE USE IN FOODS FOR INFANTS AND CHILDREN****CAC/GL 10-1979 (amended 1983, 1991)***Prepared by Germany***Introduction:**

The present document was revised on the basis of written comments and contributions to the discussion made at the last session and is hereby presented for discussion again in an amended form:

Since the Committee could not reach an agreement at the last meeting as to whether other references for purity criteria apart from the globally recognized JECFA criteria should be accepted, all substances without a JECFA evaluation so far were placed in square brackets in the revised "Advisory Lists". All substances with a JECFA evaluation are in bold face. An enquiry to the JECFA showed that this Committee is ready to also make assessments of the still outstanding substances. However, the CCNFSDU is not entitled to issue a mandate for this, but only the Codex Alimentarius Commission.

No purity criteria at all could be found for a number of the listed nutrient sources. The Committee has not yet decided whether to continue to include these substances in the lists or not. In the present document the substances concerned were placed in square brackets.

In line with the CCNFSDU proposal at the 25<sup>th</sup> meeting, the "Advisory List of Food Additives for Special Vitamin Forms" was deleted. The reason given was that it was not the responsibility of the Committee to draft a list of food additives. The Canadian delegation did not agree to this. We think that this point requires further discussion.

The Committee has not yet reached a consensus as to whether the use of nutrients should also be indicated for the category "foods for special medical purposes – FSMP" and whether nutrient sources specifically suitable for the use in FSMP should be listed.

***ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN*****1. PREAMBLE**

These lists include nutrient compounds, which may be used for nutritional purposes in foods for special dietary uses intended for use by infants and young children in accordance with 1) the criteria and conditions of use identified below and 2) other criteria for their use stipulated in the respective standards. As noted in the respective standards, their use may either be essential or optional.

**2. CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS**

2.1 Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:

- (a) they are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children
- (b) it is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available
- (c) the purity requirements of the nutrient compounds are established in an internationally recognised specification or, if there is no internationally recognised specification, national purity requirements may be considered

(d) the stability of nutrient compounds in the food(s) in which it is/they are to be used can be demonstrated

(e) the fulfilment of the above criteria shall be demonstrated by generally accepted scientific criteria.

2.2 Nutrient compounds shall be deleted from the Lists if they are found no longer to meet the above criteria. Nutrient compounds may be added to the Lists based on the criteria above.

**A: ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN**

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>1. Source of Calcium (Ca)</b>						
<b>1.1 Calcium carbonate</b>	<b>Ph Eur (2002), USP/NF, FCC IV, DAB, BP, JECFA (1973)</b>	√	√	√	√	[√]
<b>1.2 Calcium chloride</b>	<b>Ph Eur (2002), USP, FCC IV, DAB, JP, BP, JECFA (1975)</b>	√	√	√	√	[√]
<b>1.3 Tricalcium dicitrate (Calcium citrate)</b>	<b>USP, FCC IV, DAC, JECFA (1975)</b>	√	√	√	√	[√]
<b>1.4 Calcium gluconate</b>	<b>Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1998)</b>	√	√	√	√	[√]
[1.5 Calcium glycerophosphate]	[Ph Eur (2002), FCC IV, Ph Franc]	[√]	[√]	[√]	[√]	[√]
<b>1.6 Calcium lactate*</b>	<b>Ph Eur (2002) (Tri- and Pentahydrate), USP, FCC IV, BP, DAB, JECFA (1974)</b>	√	√	√	√	[√]
<b>1.7 Calcium hydroxide</b>	<b>Ph Eur (2002), USP, FCC IV, BP, JECFA (1975)</b>	√	√	√	√	[√]
<b>1.8 Calcium oxide</b>	<b>FCC IV, DAC, JECFA (1975)</b>	-	-	√	√	-
<b>1.9 Calcium dihydrogen phosphate (Calcium phosphate, monobasic)</b>	<b>FCC IV, JECFA (1996)</b>	√	√	√	√	[√]
<b>1.10 Calcium hydrogen phosphate (Calcium phosphate, dibasic)</b>	<b>Ph Eur (2002), USP, FCC IV, BP, DAB, JECFA (1975)</b>	√	√	√	√	[√]
<b>1.11 Tricalcium diphosphate (Calcium phosphate, tribasic)</b>	<b>BP, FCC IV, JECFA (1973)</b>	√	√	√	√	[√]
<i>Other calcium compounds proposed for inclusion:</i>						
[1.12 Calcium citrate malate]	?	-	-	-	-	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
[1.13 Calcium enriched yeast]	?	-	-	-	-	[√]
[1.14 Calcium pyruvate monohydrate]	?	-	-	-	-	[√]
<b>Malaysia:</b> <b>1.15 Calcium pyrophosphate</b>	<b>FCC IV, JECFA (1980)</b>	?	?	?	?	?
<b>Neuseeland, Malaysia, ISDI:</b> <b>1.16 Calcium sulphate</b>	<b>Ph Eur (2002) (dihydrate), FCC IV, DAB, JECFA (1975)</b>	-	-	-	-	[√]
<b>2. Source of Iron (Fe)</b>						
[2.1 Ferrous carbonate, stabilised with saccharose]	?	-	-	[√]	[√]	[√]
[2.2 Ferrous fumarate]	[Ph Eur (2002), BP, USP, FCC IV]	[√]	[√]	[√]	[√]	[√]
<b>2.3 Ferrous gluconate</b>	<b>Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1999)</b>	√	√	√	√	[√]
<b>2.4 Ferrous lactate</b>	<b>NF, FCC IV, JECFA (1989)</b>	√	√	√	√	[√]
<b>2.5 Ferrous sulphate</b>	<b>Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1999)</b>	√	√	√	√	[√]
<b>2.6 Ferric ammonium citrate</b>	<b>DAC, FCC IV, JECFA (1984)</b>	√	√	√	√	[√]
[2.7 Ferric citrate]	[FCC IV]	[√]	[√]	[√]	[√]	[√]
[2.8 Ferric diphosphate (pyrophosphate)]	[FCC IV]	[√]	[√]	[√]	[√]	[√]
[2.9 Hydrogen reduced iron]	[FCC IV, DAB]	-	-	[√]	[√]	[√]
[2.10 Electrolytic iron]	[FCC IV]	-	-	[√]	[√]	[√]
[2.11 Carbonyl iron]	[FCC IV]	-	-	[√]	[√]	[√]
[2.12 Ferric saccharate]	?	-	-	[√]	[√]	[√]
[2.13 Ferric orthophosphate]	[FCC IV]	?	?	?	?	?
<i>Other iron compounds proposed for inclusion:</i>						

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
EU, ISDI: [2.14 Sodium ferric diphosphate]	[FCC IV]	-	-	[√]	[√]	[√]
ISDI: [2.15 Ferrous citrate]	[FCC IV]	[√]	[√]	[√]	[√]	[√]
New Zealand: [2.16 Ferrous succinate]	?	?	?	?	?	?
<b>3. Source of Magnesium (Mg)</b>						
<b>3.1 Magnesium hydroxide carbonate</b>	<b>BP, USP, DAB, JECFA (1983)</b>	√	√	√	√	[√]
<b>3.2 Magnesium chloride</b>	<b>Ph Eur (2002) (-4,5-hydrate), USP, FCC IV, DAB, BP, JECFA (1983)</b>	√	√	√	√	[√]
[3.3 Trimagnesium dicitrate (Magnesium citrate)]	[DAC]	[√]	[√]	[√]	[√]	[√]
<b>3.4 Magnesium gluconate</b>	<b>FCC IV, DAC, JECFA (1999)</b>	√	√	√	√	[√]
[3.5 Magnesium glycerophosphate]	[Ph Eur (2002), BPC]	-	-	[√]	[√]	[√]
<b>3.6 Magnesium hydroxide</b>	<b>Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1975)</b>	√	√	√	√	[√]
<b>3.7 Magnesium lactate</b>	<b>JECFA (Mg-DL-Lactat, Mg-L-Lactat: 1983)</b>			√	√	[√]
<b>3.8 Magnesium oxide</b>	<b>Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1973)</b>	√	√	√	√	[√]
<b>3.9 Magnesium hydrogen phosphate (Magnesium phosphate, dibasic)</b>	<b>FCC IV, DAB, JECFA (1982)</b>	√	√	√	√	[√]
<b>3.10 Trimagnesium diphosphate (Magnesium phosphate, tribasic)</b>	<b>FCC IV, JECFA (1973)</b>	√	√	√	√	[√]
[3.11 Magnesium sulphate]	[Ph Eur (2002) (Heptahydrate), BP, USP, JP, FCC IV, DAB, DAC]	[√]	[√]	[√]	[√]	[√]
[3.12 Magnesium acetate]	[DAC]	-	-	-	-	[√]
[3.13 Magnesium salts of citric acid]	?	[√]	[√]	[√]	[√]	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<i>Other magnesium compounds proposed for inclusion:</i>						
<b>3.14 Magnesium carbonate</b>	<b>DAB, Ph Eur (2002), BP, USP, FCC IV, JECFA (1973)</b>	√	√	√	√	[√]
<b>4. Source of Sodium (Na)</b>						
<b>4.1 Sodium carbonate</b>	<b>Ph Eur (2002), BP, NF, FCC IV, DAB, USP, JECFA (1975)</b>	√	√	-	-	[√]
<b>4.2 Sodium hydrogen carbonate (Sodium bicarbonate)</b>	<b>Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1975)</b>	√	√	-	-	[√]
[4.3 Sodium chloride]	[Ph Eur (2002), BP, JP, USP/NF, FCC IV, DAB]	[√]	[√]	-	-	[√]
<b>4.4 Trisodium citrate (Sodium citrate)</b>	<b>Ph Eur (2002), USP, FCC IV, BP, DAB, JECFA (1975)</b>	√	√	-	-	[√]
<b>4.5 Sodium gluconate</b>	<b>USP, FCC IV, DAC, JECFA (1998)</b>	√	√	-	-	[√]
<b>4.6 Sodium lactate*</b>	<b>Ph Eur (2002), BP, USP, FCC IV, DAB, JECFA (1974)</b>	√	√	-	-	[√]
<b>4.7 Sodium dihydrogen phosphate (Sodium phosphate, monobasic)</b>	<b>Ph Eur (2002) (Dihydrate), USP, FCC IV, JECFA (1963)</b>	√	√	-	-	[√]
<b>4.8 Disodium hydrogen phosphate (Sodium phosphate, dibasic)</b>	<b>USP, FCC IV, BP, JECFA (1975)</b>	√	√	-	-	[√]
<b>4.9 Trisodium phosphate (Sodium phosphate, tribasic)</b>	<b>FCC IV, DAC, JECFA (1975)</b>	√	√	-	-	[√]
<b>4.10 Sodium hydroxide</b>	<b>Ph Eur (2002), DAB, NF, JP, BP, USP, FCC IV, JECFA (1975)</b>	√	√	-	-	[√]
<i>Other sodium compounds proposed for inclusion:</i>						
New Zealand: [4.11 Sodium chloride (iodised)]	[Ph Eur (2002), BP, JP, USP]	?	?	?	?	?
<b>4.12 Sodium sulphate</b>	<b>Ph Eur (2002), DAB, BP, FCC IV, USP, JECFA (2000)</b>	?	?	?	?	?
<b>4.13 Sodium tartrate</b>	<b>JECFA (1963)</b>	?	?	?	?	?

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>5. Source of Potassium (K)</b>						
<b>5.1 Potassium carbonate</b>	Ph Eur (2002), USP, FCC IV, DAC, JECFA (1975)	√	√	-	-	[√]
<b>5.2 Potassium hydrogen carbonate (Potassium bicarbonate)</b>	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1975)	√	√	-	-	[√]
<b>5.3 Potassium chloride</b>	Ph Eur (2002), USP, FCC IV, BP, DAB, JECFA (1979)	√	√	√	√	[√]
<b>5.4 Tripotassium citrate (Potassium citrate)</b>	Ph Eur (2002), USP, FCC IV, DAB, BP, JECFA (1975)	√	√	√	√	[√]
<b>5.5 Potassium gluconate</b>	USP, FCC IV, DAC, JECFA (1998)	√	√	√	√	[√]
[5.6 Potassium glycerophosphate]	[FCC IV]	-	-	[√]	[√]	[√]
<b>5.7 Potassium lactate*</b>	FCC IV, DAB, JECFA (1974)	√	√	√	√	[√]
<b>5.8 Potassium dihydrogen phosphate (Potassium phosphate, monobasic)</b>	Ph Eur (2002), FCC IV, NF, BP, DAB, JECFA (1976)	√	√	-	-	[√]
<b>5.9 Dipotassium hydrogen phosphate (Potassium phosphate, dibasic)</b>	FCC IV, BP, JECFA (1975)	√	√	-	-	[√]
<b>5.10 Potassium phosphate, tribasic</b>	JECFA (1975)	√	√	-	-	[√]
<b>5.11 Potassium hydroxide</b>	Ph Eur (2002), BP, JP, NF, FCC IV, DAC, JECFA (1975)	√	√	-	-	[√]
<b>6. Source of Copper (Cu)</b>						
[6.1 Cupric carbonate]	?	[√]	[√]	[√]	[√]	[√]
[6.2 Cupric citrate]	[FCC IV]	[√]	[√]	[√]	[√]	[√]
[6.3 Cupric gluconate (Copper gluconate)]	[FCC IV]	[√]	[√]	[√]	[√]	[√]
[6.4 Copper-lysine-complex]	?	[√]	[√]	[√]	[√]	[√]
<b>6.5 Cupric sulphate (Copper sulphate)</b>	Ph Eur (2002), USP, FCC IV, DAB, JECFA (1973)	√	√	√	√	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>7. Source of Iodine (I)</b>						
[7.1 Potassium iodide]	[Ph Eur (2002), BP, USP, FCC IV, DAB]	[√]	[√]	[√]	[√]	[√]
[7.2 Sodium iodide]	[Ph Eur (2002), USP, BP, DAB]	[√]	[√]	[√]	[√]	[√]
<b>7.3 Potassium iodate</b>	<b>FCC IV, JECFA (1988)</b>	√	√	√	√	[√]
[7.4 Sodium iodate]		-	-	[√]	[√]	[√]
<b>8. Source of Zinc (Zn)</b>						
[8.1 Zinc acetate]	[Ph Eur (2002) (Dihydrate), USP]	[√]	[√]	[√]	[√]	[√]
[8.2 Zinc chloride]	[Ph Eur (2002), USP, BP, JP, DAB]	[√]	[√]	[√]	[√]	[√]
[8.3 Zinc citrate]	[FCC IV]	[√]	[√]	[√]	[√]	[√]
[8.4 Zinc gluconate]	[USP, FCC IV, DAC]	[√]	[√]	[√]	[√]	[√]
[8.5 Zinc lactate]	?	[√]	[√]	[√]	[√]	[√]
[8.6 Zinc oxide]	[Ph Eur (2002), BP, USP, FCC IV, DAB]	[√]	[√]	[√]	[√]	[√]
[8.7 Zinc sulphate]	[Ph Eur (2002), BP, USP, FCC IV]	[√]	[√]	[√]	[√]	[√]
<i>Other zinc compounds proposed for inclusion:</i>						
EU, ISDI:						
[8.8 Zinc carbonate]	?	-	-	-	-	[√]
<b>9. Source of Manganese (Mn)</b>						
[9.1 Manganese(II) carbonate]	?	[√]	[√]	[√]	[√]	[√]
[9.2 Manganese(II) chloride]	[FCC IV]	[√]	[√]	[√]	[√]	[√]
[9.3 Manganese(II) citrate]	[FCC IV]	[√]	[√]	[√]	[√]	[√]
[9.4 Manganese(II) glycerophosphate]	[FCC IV]	-	-	[√]	[√]	[√]
[9.5 Manganese(II) sulphate]	[Ph Eur (2002) (Monohydrate), USP, FCC IV]	[√]	[√]	[√]	[√]	[√]



Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
[9.6 Manganese(II) gluconate]	[FCC IV]	[√]	[√]	[√]	[√]	[√]
<b>10. Source of Selenium (Se)</b>						
[10.1 Sodium selenate]	?	[√]	[√]	New Zealand[ √]	-	[√]
[10.2 Sodium selenite]	[DAC]	√	√	New Zealand[ √]	-	[√]
[10.3 Sodium hydrogen selenite]	?	ISDI: [√]	ISDI: [√]	ISDI: [√]	ISDI: [√]	[√]
<i>Other selenium compounds proposed for inclusion:</i>						
ISDI: [10.4 Selenium enriched yeast]	?	-	-	-	-	[√]
<b>11. Chromium (Cr III)</b>						
[11.1 Chromium (III) sulphate and its hexahydrate]	?	-	-	-	-	[√]
[11.2 Chromium (III) chloride and its hexahydrate]	?	-	-	-	-	[√]
<i>Other chromium compounds proposed for inclusion:</i>						
ISDI: [11.3 Chromium enriched yeast]	?	-	-	-	-	[√]
<b>12. Molybdenum (Mo VI)</b>						
[12.1 Sodium molybdate]	[Ph Eur (2002) (dihydrate), BP, DAB]	-	-	-	-	[√]
[12.2 Ammonium molybdate]	[USP, FCC IV]	-	-	-	-	[√]
<b>13. Fluoride (F)</b>						
[13.1 Potassium fluoride]	?	-	-	-	-	[√]
[13.2 Sodium fluoride]	[Ph Eur (2002), BP, USP, DAB, FCC IV]	-	-	-	-	[√]
<i>Other fluoride compounds proposed for inclusion:</i>						
ISDI: [13.3 Calcium fluoride]	[DAB]	-	-	-	-	[√]

\* Nutrient compounds that should not be used in infant foods, as proposed by the United States during the 24<sup>th</sup> Session of the CCNSFDU.

**B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN**

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>1. Vitamin A</b>						
[1.1 all trans Retinol]	[Ph Eur (2002) (vitamin A), USP, FCC IV (vitamin A)]	[√]	[√]	[√]	[√]	[√]
[1.2 Retinyl acetate]	[Ph Eur (2002) (vitamin A), USP, FCC IV (vitamin A), Jap Food Stan]	[√]	[√]	[√]	[√]	[√]
[1.3 Retinyl palmitate]	[Ph Eur (2002) (vitamin A), USP, FCC IV (vitamin A), Jap Food Stan]	[√]	[√]	[√]	[√]	[√]
<b>2. Provitamin A</b>						
<b>2.1 Beta-Carotene</b>	<b>Ph Eur (2002), USP, FCC IV, Jap Food Stan, JECFA (1987)</b>	√	√	√	√	[√]
<i>Other provitamin A carotenoids proposed for inclusion:</i>						
<b>ISDI:</b> <b>2.2 Provitamin A other than beta-carotene</b>	<b>FCC IV (□-apo-8-carotenal), JECFA (1984) (□-apo-8-carotenal)</b>	√	√	√	√	[√]
<b>3. Vitamin D</b>						
[3.1 Vitamin D2 = Ergocalciferol]	[Int.Pharm, Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB]	[√]	[√]	[√]	[√]	[√]
[3.2 Vitamin D3 = Cholecalciferol]	[BP, USP, Int.Pharm, FCC IV, Jap Food Stan, DAB]	[√]	[√]	[√]	[√]	[√]
<i>Other vitamin D compounds proposed for inclusion:</i>						
New Zealand: [3.3 Cholecalciferol cholesterol]	?	?	?	?	?	?

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>4. Vitamin E</b>						
<b>4.1 D-alpha-Tocopherol</b>	<b>Ph Eur (2002), USP, FCC IV, JECFA (2000)</b>	√	√	√	√	[√]
<b>4.2 DL-alpha-Tocopherol</b>	<b>Ph Eur (2002), USP, FCC IV, Jap Food Stan, JECFA (1986)</b>	√	√	√	√	[√]
[4.3 D-alpha-Tocopheryl acetate]	[Ph Eur (2002), USP, FCC IV]	[√]	[√]	[√]	[√]	[√]
[4.4 DL-alpha-Tocopheryl acetate]	[Ph Eur (2002), USP, FCC IV; NF, BP]	[√]	[√]	[√]	[√]	[√]
<i>Other tocopheryl compounds proposed for inclusion:</i>						
ISDI, EU, New Zealand: [4.5 D-alpha-Tocopheryl acid succinate]	[NF, FCC IV]	-	-	-	-	[√]
[4.6 DL-alpha-Tocopheryl acid succinate]	?	-	-	-	-	[√]
<b>5. Vitamin C</b>						
<b>5.1 L-Ascorbic acid</b>	<b>Ph Eur (2002), BP, USP, JP, FCC IV, Int. Pharm, Jap Food Stan, DAB, JECFA (1973)</b>	√	√	√	√	[√]
<b>5.2 Calcium-L-ascorbate</b>	<b>Ph Eur (2002), USP, FCC IV, JECFA (1981)</b>	√	√	√	√	[√]
[5.3 Potassium-L-ascorbate]	?	[√]	[√]	[√]	[√]	[√]
<b>5.4 6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate)</b>	<b>Ph Eur (2002), BP, NF, FCC IV, USP/NF, Jap Food Stan, DAB, JECFA (1973)</b>	√	√	√	√	[√]
<b>5.5 Sodium-L-ascorbate</b>	<b>DAC, Ph Franc, USP, FCC IV, Ph Eur (2002), Jap Food Stan, JECFA (1973)</b>	√	√	√	√	[√]
<b>6. Vitamin B<sub>1</sub></b>						
[6.1 Thiaminchloride hydrochloride]	[Int. Pharm, Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB]	[√]	[√]	[√]	[√]	[√]
[6.2 Thiamin mononitrate]	[Int. Pharm, Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB]	[√]	[√]	[√]	[√]	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>7. Vitamin B<sub>2</sub></b>						
<b>7.1 Riboflavin</b>	<b>Ph Eur (2002), BP, JP, USP, Int. Pharm, FCC IV, Jap Food Stan, DAB, JECFA (1987)</b>	√	√	√	√	[√]
<b>7.2 Riboflavin-5'-phosphate sodium</b>	<b>Ph Eur (2002), BP, JP, USP, Jap Food Stan, DAB, JECFA (1987)</b>	√	√	√	√	[√]
<b>8. Niacin</b>						
[8.1 Nicotinic acid amide (Nicotinamide)]	[Ph Eur (2002), BP, USP, FCC IV, Int. Pharm, Jap Food Stan, DAB]	[√]	[√]	[√]	[√]	[√]
[8.2 Nicotinic acid]	[Ph Eur (2002), BP, USP, Int. Pharm, FCC IV, Jap Food Stan, DAB]	[√]	[√]	[√]	[√]	[√]
<b>9. Vitamin B<sub>6</sub></b>						
[9.1 Pyridoxine hydrochloride]	[Int. Pharm, Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB]	[√]	[√]	[√]	[√]	[√]
[9.2 Pyridoxal 5-phosphate]	?	[√]	[√]	[√]	[√]	[√]
[9.3 Pyridoxal dipalmitate]	?	[√]	[√]	[√]	[√]	[√]
<i>Other pyridoxine compounds proposed for inclusion:</i>						
Malaysia: [9.4 Pyridoxamine]	?	?	?	?	?	?
<b>10. Folic acid</b>						
[10.1 N-Pteroyl-L-glutamic acid]	[Ph Eur (2002), USP, FCC IV, Jap Food Stan]	[√]	[√]	[√]	[√]	[√]
<b>11. Pantothenic acid</b>						
[11.1 Calcium-D-pantothenate]	[Ph Eur (2002), USP, FCC IV, Jap Food Stan, DAB]	[√]	[√]	[√]	[√]	[√]
[11.2 Sodium-D-pantothenate]	[Jap Food Stan, DAB]	[√]	[√]	[√]	[√]	[√]
[11.3 D-Panthenol/DL-Panthenol]	[Ph Eur (2002), USP, FCC IV]	[√]	[√]	[√]	[√]	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>12. Vitamin B<sub>12</sub></b>						
[12.1 Cyanocobalamin]	[Ph Eur (2002), BP, USP, FCC IV, DAB]	[√]	[√]	[√]	[√]	[√]
[12.2 Hydroxocobalamin]	[Ph Eur (2002) (Hydrochloride), USP, NF]	[√]	[√]	[√]	[√]	[√]
<b>13. Vitamin K<sub>1</sub></b>						
[13.1 Phytomenadione (2-Methyl-3-phytyl-1,4-naphthoquinone/Phylloquinone)]	[Ph Eur (2002), BP, USP, FCC IV ( <u>vitamin K</u> )]	[√]	[√]	[√]	[√]	[√]
<b>14. Biotin</b>						
[14.1 D-Biotin]	[Ph Eur (2002), USP, FCC IV]	[√]	[√]	[√]	[√]	[√]

**C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN**

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>1. Amino acids</b>						
1.1 L-Arginine]	[Ph Eur (2002), BP, USP, FCC IV, DAB]	}				[√]
1.2 L-Arginine hydrochloride]	[Ph Eur (2002), BP, USP, FCC IV, DAB]					[√]
1.3 L-Cystine]	[Ph Eur (2002), USP, FCC IV]					[√]
1.4 L-Cystine dihydrochloride]	?					[√]
1.5 L-Cysteine]	[DAB]					[√]
1.6 L-Cysteine hydrochloride]	[Ph Eur (2002), FCC]					[√]
1.7 L- Histidine]	[Ph Eur (2002), USP, FCC IV, DAB]					[√]
1.8 L- Histidine hydrochloride]	[Ph Eur (2002), FCC IV, DAB]					[√]

only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children					
		IF	FUF	PCBF	CBF	FSMP	
1.9 L-Isoleucine]	[Ph Eur (2002), USP, FCC IV, DAB]	}				[√]	
1.10 L-Isoleucine hydrochloride]	?						[√]
1.11 L-Leucine]	[Ph Eur (2002), USP, FCC IV, DAB]						[√]
1.12 L-Leucine hydrochloride]	?						[√]
1.13 L-Lysine]	[USP]						[√]
1.14 L-Lysine monohydrochloride[]]	[Ph Eur (2002), USP, FCC IV, DAB]						[√]
1.15 L-Methionine]	[Ph Eur (2002), USP, FCC IV, DAB]						[√]
1.16 L-Phenylalanine]	[Ph Eur (2002), USP, FCC IV]						[√]
1.17 L-Threonine]	[Ph Eur (2002), USP, FCC IV, DAB]						[√]
1.18 L-Tryptophan]	[Ph Eur (2002), USP, FCC IV, DAB]						[√]
1.19 L-Tyrosine]	[Ph Eur (2002), USP, FCC IV, DAB]						[√]
1.20 L-Valine]	[Ph Eur (2002), USP, FCC IV, DAB]						[√]
<i>Other amino acids and their derivatives proposed for inclusion:</i>							
ISDI: [1.21 L-Alanine]	[Ph Eur (2002), USP, FCC IV, DAB]			-		[√]	
[1.22 L-Arginine L-aspartate]	?			-		[√]	
[1.23 L-Aspartic acid]	[Ph Eur (2002), USP, FCC IV]			-		[√]	
[1.24 L-Citrulline]	[USP, DAC]			-		[√]	
<b>1.25 L- Glutamic acid</b>	<b>Ph Eur (2002), USP, FCC IV, JECFA (1987)</b>	<b>ISDI: [√]</b>	<b>ISDI: [√]</b>			[√]	
[1.26 L-Glutamine]	[USP, FCC IV, DAB]	ISDI: [√]	ISDI: [√]			[√]	
[1.27 Glycine]	[Ph Eur (2002), USP, FCC IV]			-		[√]	
[1.28 L-Lysine acetate]	?	ISDI: [√]	ISDI: [√]	ISDI: [√]	ISDI: [√]	[√]	

only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use)

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
[1.29 L-Lysine L-Aspartate]	?			-		[√]
[1.30 L-Lysine L-Glutamate dihydrate]	?			-		[√]
[1.31 L-Ornithine]	?			-		[√]
[1.32 L-Proline]	[Ph Eur (2002), USP, FCC IV, DAB]			-		[√]
[1.33 L-Serine]	[PH Eur (2002), USP, DAB]			-		[√]
[1.34 N-Acetyl-L-cysteine]	[Ph Eur (2002), USP, DAB]			-		[√]
[1.35 N-Acetyl-L-methionine]	[FCC IV]			-		[√] except infants
[1.36 S-Adenosyl-L-methionine]	?			-		[√] except infants
<b>2. Carnitine</b>						
[2.1 L-Carnitine]	[USP, FCC IV]	[√]	[√]	ISDI: [√]	ISDI: [√]	[√]
[2.2 L-Carnitine hydrochloride]	?	[√]	[√]	ISDI: [√]	ISDI: [√]	[√]
<i>Other carnitine compounds proposed for inclusion:</i>						
ISDI: [2.3 L-Carnitine tartrate]	?	-	-	-	-	[√]
<b>3. Taurine</b>						
[3.1 Taurine]	[USP, JP]	[√]	ISDI: [√]	-	-	[√]
<b>4. Choline</b>						
[4.1 Choline]		[√]	[√]	[√]	[√]	[√]
[4.2 Choline chloride]	[DAB 1996, FCC IV, DAC]	[√]	[√]	[√]	[√]	[√]
[4.3 Choline citrate]	[NF]	[√]	[√]	[√]	[√]	[√]
[4.4 Choline hydrogen tartrate]	[DAB 1996]	[√]	[√]	[√]	[√]	[√]
[4.5 Choline bitartrate]	[DAB 1996, FCC IV, NF]	[√]	[√]	[√]	[√]	[√]

Nutrient Source	Purity Requirements	Use in Food Categories for Infants and Young Children				
		IF	FUF	PCBF	CBF	FSMP
<b>[5. Myo-Inositol</b> (=meso-Inositol)]	[DAC, FCC IV]	[√]	[√]	[√]	[√]	[√]
<b>6. Nucleotides</b>						
[6.1 Cytidine 5-monophosphate (CMP)]		[√]	ISDI: [√]	-	-	[√]
[6.2 Cytidine 5-monophosphate sodium salt]		[√]	ISDI: [√]	-	-	[√]
[6.3 Uridine 5-monophosphate (UMP)]		[√]	ISDI: [√]	-	-	[√]
[6.4 Uridine 5-monophosphate sodium salt]		[√]	ISDI: [√]	-	-	[√]
[6.5 Adenosine 5- monophosphate (AMP)]		[√]	ISDI: [√]	-	-	[√]
[6.6 Adenosine 5- monophosphate sodium salt]		[√]	ISDI: [√]	-	-	[√]
<b>[6.7 Guanosine 5- monophosphate (GMP)</b>	<b>JECFA (1985)</b>	√	<b>ISDI:</b> [√]	-	-	[√]
[6.8 Guanosine 5- monophosphate sodium salt]		[√]	ISDI: [√]	-	-	[√]
<b>[6.9 Inosine 5-monophosphate (IMP)</b>	<b>JECFA (1974)</b>	√	<b>ISDI:</b> [√]	-	-	[√]
[6.10 Inosine 5- monophosphate sodium salt]		[√]	ISDI: [√]	-	-	[√]
ISDI: <b>[7. Creatine monohydrate]</b>						[√]



**Abbreviations:**

IF	=	infant formula
FUF	=	follow-up formula
PCBF	=	processed cereal based food
CBF	=	canned baby food
[FSMP]	=	food for special medical purposes
BP	=	British Pharmacopoeia
BPC	=	British Pharmaceutical Codex
DAB	=	Deutsches Arzneibuch
DAC	=	Deutscher Arzneimittel-Codex
FCC	=	Food Chemicals Codex
FU	=	Farmacopoea Ufficiale della Repubblica Italiana
JP	=	The Pharmacopeia of Japan
Jap Food Stan	=	Japanese Food Standard
NF	=	The National Formulary/USA
Ph Eur	=	Pharmacopoeia Europaea
Ph Franç	=	Pharmacopée Française
Ph Helv	=	Pharmacopoea Helvetica
Ph Int	=	International Pharmacopeia
USP	=	The United States Pharmacopeia