

**SPECIFICATIONS FOR INFANT FORMULA AND FOLLOW ON FORMULA NOTIFIED IN
G/SPS/N/KOR/457**

12-2 Infant formula

Specifications

- (1) Characteristics: Shall have distinctive color and flavor and be free of foreign taste or odor
- (2) Water content (%): not more than 5.0 (applicable only to powdery products)
- (3) Crude protein (g/100kcal): 1.8-4.0
- (4) Crude fat (g/100kcal): 3.3-6.0 Extension to range to 3.0 -6.0 proposed.
- (5) Linoleic acid (mg/100kcal): not less than 300 Minimum is the same, New maximum limit of 1400
Unknown word (g/100kcal)– 120 or more – not underlined as new
 - (6) Vitamin A (IU/100kcal or µg/100kcal): 250-500 or 75-150 Extension to range to 200~600 IU/100kcal or 60~180 µg/100kcal
- (7) Vitamin D (IU/100kcal or µg/100kcal):40-100 or 1-2.5
- (8) Vitamin C (mg/100kcal): not less than 8 Proposed to be not less than 10
- (9) Vitamin B₁ (mg/100kcal): not less than 40 Minimum increased to 60 mg/100kcal. New maximum proposed of 300 mg/100kcal
- (10) Vitamin B₂ (mg/100kcal): not less than 60. Proposed minimum of 80 and maximum of 500 mg/100kcal
- (11) Nicotinic acid (µg/100kcal): not less than 250 New name of Niacin. New minimum of 300 and maximum of 1500 µg/100kcal
- (12) Vitamin B₆ (µg/100kcal): not less than 35 (however, when protein is 2.3g or more, the B₆ content shall increase by 15µg per gram of protein exceeding 2.3g) Proposed new maximum of 175 µg/100kcal (notes appear the same).
- (13) Folic acid (µg/100kcal): not less than 4.0. Amendment to minimum so not less than 10 µg/100kcal and addition of a maximum of 50 µg/100kcal
- (14) Pantothenic acid (µg/100kcal): not less than 300. Amendment to minimum so not less than 400 µg/100kcal: and addition of a maximum of 2000 µg/100kcal:
- (15) Vitamin B₁₂ (µg/100kcal): not less than 0.1
- (16) Vitamin K₁ (µg/100kcal): not less than 4.0. Addition of a maximum of 27 µg/100kcal.
- (17) Biotin (µg/100kcal): not less than 1.5 Not mentioned in the table
- (18) Choline (mg/100kcal): not less than 7.0.
- (19) Vitamin E (IU/100kcal): not less than 0.7 (however, if linoleic acid is 1g or more, the ratio of Vitamin E to linoleic acid shall be 0.71IU to 1 g.) Minimum is amended to be between 0.5 or 0.7.0 mg/100kcal, maximum is 5.0 or 7.0 (notes appear the same)
- (20) Sodium (mg/100kcal): 20-60
- (21) Potassium (mg/100kcal): 80-200 Range is amended to be 60-180 mg/100kcal
- (22) Chloride (mg/100kcal): 55-150 Range is amended to be 50-160 mg/100kcal
- (23) Calcium (mg/100kcal): not less than 50. A new maximum is proposed of 140 Range is amended to be 60-180 mg/100kcal
- (24) Phosphorus (mg/100kcal): not less than 25 (however, the ratio between calcium and phosphorus (Ca:P) shall be 1.2-2.0). A new maximum is proposed of 100 mg/100kcal. ((However, the ratio of calcium and phosphorus should be 1:01 to 2:01)
- (25) Magnesium (mg/100kcal): not less than 6.0. The proposed minimum is 5.0 mg/100kcal. A new maximum of 15 mg/100kcal is proposed.
- (26) Iron (mg/100kcal): not less than 1.0 This is amended to be not less than 0.45 (or

not less than 1.0 for iron fortified products)

(27) Iodine ($\mu\text{g}/100\text{kcal}$): not less than 5.0. Proposed amendment where the minimum is 10.00 and the maximum is 60 $\mu\text{g}/100\text{kcal}$.

(28) Copper ($\mu\text{g}/100\text{kcal}$): not less than 60. The minimum is now reduced to 35.

(29) Zinc ($\text{mg}/100\text{kcal}$): not less than 0.75. Proposed amendment where the minimum is 0.5 and the maximum is 15 $\text{mg}/100\text{kcal}$.

(30) Manganese ($\mu\text{g}/100\text{kcal}$): not less than 5. Proposed amendment where the minimum is 1.00 and the maximum is 100 $\mu\text{g}/100\text{kcal}$.

Proposed new limit for Selenium – the minimum is 1.0 and the maximum is 9.0 $\mu\text{g}/100\text{kcal}$

(30) Artificial sweetener: Should not be detected.

(31) Tar color: Should not be detected.

(32) The number of bacteria: Not more than 20,000 per 1g (Negative in case of liquefied products) Amended to $n = 5$, $c = 2$, $m = 1,000 / \text{g}$, $M = 10,000 / \text{g}$ (prepared milk should be the negative - however, lactic acid bacteria should be excluded for Lactobacillus added products)

(33) Coliform group: Negative

(34) Enterobacter Sakazakii: Negative (Limited to powdery product among infant formula for infants less than 6 months) $n = 5$, $c = 0$, $m = 0/60\text{g}$ (limited to formula)

(35) Bacillus Cereus: Not more than 100 per 1g (Excluding liquefied products)

(36) Scorched particles: Not more than 7.5 $\text{mg}/100 \text{g}$ (compared to standard disk A as specified by the USADPI) (Limited to powdered products)

12-3 Follow-up formula

Specifications

(1) Characteristics: Shall have distinctive color and flavor and be free of foreign taste or odor

(2) Water content (%): not more than 5.0 (applicable only to powdery products)

(3) Crude protein ($\text{g}/100\text{kcal}$): 3.0-5.5. Amended to 2.4 -5.5

(4) Crude fat ($\text{g}/100\text{kcal}$): 3.0-6.0

(5) Linoleic acid ($\text{mg}/100\text{kcal}$): not less than 300

Unknown word ($\text{g}/100\text{kcal}$)– 120 or more – not underlined as new

(6) Vitamin A (IU/100kcal or $\mu\text{g}/100\text{kcal}$): 250-500 or 75-225

(7) Vitamin D (IU/100kcal): 40-120 or 1.0 to 3.0

(8) Vitamin C ($\text{mg}/100\text{kcal}$): not less than 8

(9) Vitamin B₁ ($\text{mg}/100\text{kcal}$): not less than 40

(10) Vitamin B₂ ($\text{mg}/100\text{kcal}$): not less than 60

(11) Nicotinic acid ($\mu\text{g}/100\text{kcal}$): not less than 250

(12) Vitamin B₆ ($\mu\text{g}/100\text{kcal}$): not less than 45 (however, when protein is 3.0g or more, the B₆ content shall increase by 15 μg per gram of protein exceeding 3.0g)

(13) Folic acid ($\mu\text{g}/100\text{kcal}$): not less than 4.0

(14) Pantothenic acid ($\mu\text{g}/100\text{kcal}$): not less than 300

(15) Vitamin B₁₂ ($\mu\text{g}/100\text{kcal}$): not less than 0.15

(16) Vitamin K₁ ($\mu\text{g}/100\text{kcal}$): not less than 4.0

(17) Biotin ($\mu\text{g}/100\text{kcal}$): not less than 1.5

(18) Vitamin E (IU/100kcal): not less than 0.7 (however, if linoleic acid is 1g or more, the ratio of Vitamin E to linoleic acid shall be 0.71IU to 1 g.)

(19) Sodium ($\text{mg}/100\text{kcal}$): 20-85

(20) Potassium ($\text{mg}/100\text{kcal}$): not less than 80

(21) Chloride ($\text{mg}/100\text{kcal}$): 55-150. Amended to be at least 55

- (22) Calcium (mg/100kcal): not less than 55. Amended to be at least 90
- (23) Phosphorus (mg/100kcal): not less than 60 (however, the ratio between calcium and phosphorus (Ca:P) shall be 1.2-2.0)
- (24) Magnesium (mg/100kcal): not less than 6.0
- (25) Iron (mg/100kcal): not less than 1.0. Amended to be 1.0 – 2.0.
- (26) Iodine (µg/100kcal): not less than 5.0
- (27) Zinc (mg/100kcal): not less than 0.5
- (27) Artificial Sweetener: Should not be detected
- (28) Tar color: Should not be detected
- (29) The number of bacteria: Not more than 20,000 per 1 g (Negative in case of liquefied products) Amended to n = 5, c = 2, m = 1,000 / g, M = 10,000 / g (prepared milk should be the negative - however, lactic acid bacteria should be excluded for Lactobacillus added products)
- (30) Coliform group: Negative Amended to n=5, c=1, m<3, M=10
- (31) Bacillus Cereus: Not more than 100 per 1 g (Excluding liquefied products)
- (32) Scorched particles: Not more than 7.5 mg/100 g (compared to standard disk A as specified by the USADPI) (Limited to powdered products)