METRIC

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SUPERSEDING
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COMMERCIAL ITEM DESCRIPTION

FORMULA, INFANT

The U.S. Department of Agriculture (USDA) has authorized the use of this Commercial Item Description (CID).

1. SCOPE. This CID covers infant formula, packed in commercially acceptable containers, suitable for use by the Federal, State, local governments, and other interested parties.

2. PURCHASER NOTES.

2.1 Purchasers *shall specify* the following:

- Type(s), style(s), class(es), and container and packaging size(s) of infant formula products desired (Sec. 3).
- When the age requirements at the time of delivery is other than specified (Sec. 5.3.4).
- When analytical requirements are different than specified (Sec. 6).
- Manufacturer's quality assurance and plant survey (Sec. 9.1).
- Manufacturer's/distributor's certification (Sec. 9.2) or USDA certification (Sec. 9.4).

2.2 Purchasers *may specify* the following:

- Packaging requirements other than commercial (Sec. 10).

3. CLASSIFICATION. The infant formula shall conform to the following list which shall be specified in the solicitation, contract, or purchase order.

Types, styles, classes, and container and packaging sizes.

Type I - Infant formula with iron (21 Code of Federal Regulations (CFR) § 107.10 (b) (4) (i))
Type II - Infant formula with low-iron (21 CFR § 107.10 (b) (4) (ii)

Style A - Milk-based/Whey-based (for infants not allergic to milk)
Style B - Soy-based (for infants allergic to milk but not to soy)
Style C - Hypoallergenic (for infants allergic to milk and soy-based infant formulas) (21 CRF § 105.62)

Class 1 - Powder
Class 2 - Liquid, concentrate
Class 3 - Ready-to-use

Container and packaging sizes

a. Powder (1) - 30.05 g (1.06 oz) per packet, 16 packets per carton, 6 cartons per case
Powder (2) - 30.05 g (1.06 oz) per pouch, 48 pouches per case
Powder (3) - 340.19 g (12 oz) per can, 6 cans per case
Powder (4) - 396.89 g (14 oz) per can, 6 cans per case
Powder (5) - 453.59 g (16 oz) per can, 6 cans per case
Powder (6) - 907.18 g (32 oz) per can, 6 cans per case
Powder (7) - 1.134 kg (40 oz) per can, 4 cans per case
Powder (8) - Other

b. Liquid, concentrate (1) - 384.46 mL (13 fl oz) per can, 24 cans per case
Liquid, concentrate (2) - 384.46 mL (13 fl oz) per can, 12 cans per case
Liquid, concentrate (3) - 384.46 mL (13 fl oz) per can, 6 cans per case
Liquid, concentrate (4) - Other

c. Ready-to-use (1) - 236.59 mL (8 fl oz) per can, 24 cans per case
Ready-to-use (2) - 236.59 mL (8 fl oz) per can, 12 cans per case
Ready-to-use (3) - 946.35 mL (32 fl oz) per can, 6 cans per case
Ready-to-use (4) - Other

4. MANUFACTURER'S/DISTRIBUTOR'S NOTES. Manufacturer's/distributor's products *shall meet* the requirements of the:

- Salient characteristics (Sec 5).
- Analytical requirements: *as specified by the purchaser* (Sec. 6).
- Manufacturer's/distributor's product assurance (Sec. 7).
- Regulatory requirements (Sec. 8).
- Quality assurance provisions: *as specified by the purchaser* (Sec. 9).
- Packaging requirements other than commercial: *as specified by the purchaser* (Sec. 10).

5. SALIENT CHARACTERISTICS.

5.1 Processing. The infant formula shall be processed in accordance with current Good Manufacturing Practices (21 CFR Part 110). The liquid formulas shall also comply with Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (21 CFR Part 113). The infant formulas shall comply with Food and Drug Administration (FDA) Infant Formula Act of 1980 and the 1986 Amendments, the Infant Formula Program - Import and Domestic, Chapter 21 - Food Composition, Standards, Labeling and Economics, and with the following:

Foods for Special Dietary Use	21 CFR § 105.65, Subpart B
Infant Formula Quality Control Procedures	21 CFR Part 106
Infant Formula	21 CFR Part 107

5.2 Food security. The infant formula should be processed and transported in accordance with the FDA's *Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance.* *http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083075.htm*. This guidance identifies the kinds of preventive measures food manufacturers, processors, or handlers may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. The implementation of enhanced food security preventive measures provides for the security of a plant's production processes and includes the storage and transportation of pre-production raw materials, other ingredients, and postproduction finished product.

5.3 Finished product.

5.3.1 Appearance and color. The infant formula shall be of medium viscosity, be free flowing, and have a uniform consistency and appearance. All infant formulas shall possess a white to light cream color and shall be uniformly colored throughout, characteristic of the type, and class it represents.

5.3.2 Body and texture. The infant formula shall be free from gelation, which includes such factors as surface ripple, unevenness of flow, and lumpiness. The infant formula shall be free from creaming (the separation of fat), protein agglomeration (the cohesion of microscopic protein particles of sufficient size to be visible), and extraneous material. Milk-based/whey-based infant formula shall be free from coarse milk and whey-based solids precipitate or sedimentation. The powder formula shall be smooth, uniform, free from lumps, or graininess.

5.3.3 Odor and taste. At standard dilution, as applicable, **ALL CLASSES** of infant formulas shall have the normal characteristic odor and taste, free from rancidity and other undesirable odors and tastes.

5.3.4 Age requirement and shelf life. The age requirement of the infant formula at the time of shipment shall comply with FDA's regulations and requirements after packaging. Cans and can coatings shall meet FDA's requirements for safe contact with packaged infant formula. All classes of infant formulas shall have a minimum of one-year shelf life from the packaged date. Each infant formula container shall declare a "use by" date. The "use by" date is to inform purchasers and users that the infant formula, until that declared date, will contain the quantity of each nutrient as specified on the label and that the formula is otherwise of an acceptable quality. The infant formula product should be discarded when the calendar current date is after the **"**use by" date.

5.4 Foreign material. Infant formula products shall be clean, sound, wholesome, and be free from foreign material such as, but not limited to, dirt, insect parts, hair, wood, glass, or metal.

5.5 Dilution. At standard dilution, all classes of infant formulas shall supply 20 Kcal per fluid ounce.

5.5.1 Powder (Class 1). Powder infant formula shall be of suitable particle size and solubility such that it will readily disperse in warm water. Manufacturer's instructions are required for the amount of powder infant formula and water to make up a standard dilution. When prepared in accordance with label instructions, the infant formula shall supply the labeled nutritional requirements. When tested, a 25 g sample shall contain no more than 15.0 mg scorched particles when compared to the United States Scorched Particle Standards for Dry Milk http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3004472.

5.5.2 Liquid concentrate (Class 2). The concentrated liquid infant formula shall be a commercially sterile product. Standard dilution is equal parts of concentrated liquid infant formula and water. When prepared in accordance with label instructions, the infant formula shall supply the labeled nutritional requirements.

5.5.3 Ready-to-use (Class 3). The ready-to-use infant formula shall be a commercially sterile product. Ready-to-use infant formula product is ready-to-use from the primary container. The infant formula shall supply the labeled nutritional requirements.

6. ANALYTICAL REQUIREMENTS. Unless otherwise specified in the solicitation, contract, or purchase order, the analytical requirements for the infant formula products shall comply with this CID, the current Infant Formula Program - Import and Domestic, Chapter 21 - Food Composition, Standards, Labeling and Economics. All testing conducted on infant formula products shall be in compliance with the most current edition of the Official Methods of Analysis of the AOAC International, and the FDA Bacteriological Analytical Manual (BAM) approved methods specific for infant formulas currently in effect. The FDA Laboratory Information Bulletin (LIB) 4421, Determination of Melamine and Cyanuric Acid Residues in Infant Formula and FDA LIB for the Isolation and Enumeration of *Enterobacter sakazakii* from Dehydrated

Powdered Infant Formula shall be used to determine the presence of melamine and *Enterobacter sakazakii* in infant formula.

The FDA may require additional tests, as newly emerging food safety information is made available. Upon microbiological analysis, the test results of powder infant formula shall meet the following values:

Salmonella	Negative
Listeria monocytogenes	Negative
Coliforms	Not more than 10 per gram
Fecal coliforms	Not more than 3 per gram
Escherichia coli	Not more than 3 per gram
Coagulase Positive *Staphylococcus aureus*	Less than 3 per gram
Bacillus cereus	Not more than 50 per gram
Aerobic Plate Count	Not more than 500 per gram
Melamine	Negative
Enterobacter sakazakii	Negative

7. MANUFACTURER'S/DISTRIBUTOR'S PRODUCT ASSURANCE. The manufacturer/ distributor shall certify that the infant formula provided shall meet the salient characteristics of this CID, conform to their own specifications, standards, and quality assurance practices, and be the same infant formula offered for sale in the commercial market. The purchaser reserves the right to require proof of conformance.

8. REGULATORY REQUIREMENTS. The delivered infant formula products shall comply with all applicable Federal, State, and local mandatory requirements and regulations relating to the production, transportation, receiving, processing, packaging, labeling, storage, distribution, and sale of infant formula products within the commercial marketplace. The infant formula products shall comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act, the Infant Formula Act of 1980 and the 1986 Amendments, the Fair Packaging and Labeling Act, and regulations promulgated thereunder. The delivered infant formula shall comply with the allergen labeling requirements of the Federal Food, Drug, and Cosmetic Act.

9. QUALITY ASSURANCE PROVISIONS. All infant formula plants producing infant formula under this CID shall comply with all applicable requirements of the FDA Infant Formula Act of 1980 and the 1986 Amendments, and the current edition of the Infant Formula Program - Import and Domestic, Chapter 21 - Food Composition, Standards, Labeling and Economics. The production, transportation, processing, handling, sampling, analysis, labeling, and sale of infant formula products shall also comply with said regulations. *Purchaser shall specify 9.1, 9.2, or 9.3.*

9.1 Manufacturer's quality assurance and plant survey. When required in the solicitation, contract, or purchase order, the infant formula manufacturer shall be required to have their facilities inspected by USDA, Agricultural Marketing Service (AMS), Dairy Programs (DP), Dairy Grading Branch (DGB), and be eligible for listing in Section I of the AMS publication "Dairy Plants Surveyed and Approved for USDA Grading Service". *(An AMS, DP plant survey verifies that at the time of the survey, the manufacturer produces products in a clean sanitary environment in accordance with 21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food and the requirements contained in 7 CFR Part 58 General Specification for Dairy Plants Approved for USDA Inspection and Grading Service.)*

9.2 Manufacturer's/distributor's certification. When required in the solicitation, contract, or purchase order, the manufacturer/distributor will certify that the infant formula distributed meets or exceeds the requirements of this CID.

9.3 USDA certification. When required in the solicitation, contract, or purchase order that product quality, acceptability or both be determined, the USDA, AMS, DP, DGB, shall be the certifying program. DGB inspectors shall certify the quality and acceptability of the infant formula in accordance with DGB procedures which include: selecting random samples of the packaged infant formula, evaluating the samples for conformance with the salient characteristics of this CID and other contractual requirements, and documenting the findings on official DGB certificates. In addition, when required in the solicitation, contract, or purchase order, DGB inspectors will examine the infant formula for conformance to the United States Standards for Condition of Food Containers in effect on the date of the solicitation. To qualify for this option the plant must be listed in "Dairy Plants Surveyed and Approved for USDA Grading Service" (Sec. 9.1).

10. PACKAGING. Preservation, packaging, packing, labeling, and case marking shall be commercial unless otherwise specified in the solicitation, contract, or purchase order. Primary containers shall be packed in corrugated fiberboard shipping containers or corrugated fiberboard trays with plastic shrink wrap that will provide infant formula protection against loss and damage during multiple shipment, handling, and storage. Each powder infant formula container shall include a measuring scoop and be equipped with a plastic lid for use after opening. Cans of infant formula shall be free of excessive dents and distortions and free from rust or other evidence of improper storage.

11. REFERENCE NOTES.

11.1 USDA certification contact. For USDA, AMS certification, contact the **Branch Chief, DGB, DP, AMS, USDA, STOP 0230, 1400 Independence Avenue, SW, Washington, DC 20250-0230, telephone (202) 720-3171, Fax (202) 720-2643, or via E-mail: Ken.Vorget@ams.usda.gov.**

11.2 Sources of documents.

11.2.1 Source of information for nongovernmental document is as follows:

Copies of the Official Methods of Analysis of the AOAC International may be obtained from: **AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877, telephone (301) 924-7077. Internet address: http://www.aoac.org.**

11.2.2 Sources of information for governmental documents are as follows:

Applicable provisions of the Fair Packaging and Labeling Act are contained in 16 CFR, Parts 500 to 503, and the Federal Food, Drug, and Cosmetic Act are contained in 21 CFR Parts 1 to 199. These documents may be purchased from: **Superintendent of Documents, New Orders, P.O. Box 979050 St. Louis, MO 63197-9000. Credit card (Visa, MasterCard, Discover/NOVUS, and American Express) purchases may be made by calling the Superintendent of Documents on (866) 512-1800, (202) 512-1800 or on the Internet at: http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.**

Copies of the Bacteriological Analytical Manual (BAM) are available from: **FDA, Center of Food Safety and Applied Nutrition (CFSAN) on the Internet at: http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm.**

Copies of Guidance for Industry - Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance is available online from: **FDA, CFSAN on the Internet at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083075.htm.**

Copies of the United States Scorched Particle Standards for Dry Milk and the photographic aid of four prepared scorched particle filter disks are available from: **Standardization Branch, DP, AMS, USDA, STOP 0230, 1400 Independence Avenue, S.W., Washington, DC 20250-0230, telephone (202) 720-7473, Fax (202) 720-2643, or on the Internet at: http://www.ams.usda.gov/dairy/grade.htm.**

Copies of this CID, the United States Standards for Condition of Food Containers, and beneficial comments, recommendations, additions, deletions, clarifications, etc. and any data which may improve this CID are available from and/or provided to: **Director, PPD, FV, AMS, USDA, STOP 0247, 1400 Independence Avenue, SW, Washington, DC 20250-0243, telephone (202) 720-9939, Fax (202) 690-1527, via E-mail: FQAStaff@ams.usda.gov or on the Internet at: http://www.ams.usda.gov/FQAS.**

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