METRIC

A-A-20178C
March 4, 2013
SUPERSEDING
A-A-20178B
December 12, 2012

COMMERCIAL ITEM DESCRIPTION

SUGAR SUBSTITUTES, NON-CARBOHYDRATE

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

1. SCOPE. This CID covers non-carbohydrate sugar substitutes, packed in commercially acceptable containers, suitable for use by Federal, State, local governments, and other interested parties, and as a component of operational rations.

2. PURCHASER NOTES.

2.1 Purchasers *shall specify* the following:

- Type(s), style(s), and package(s) of non-carbohydrate sugar substitutes desired (Sec. 3).
- Manufacturer's/distributor's certification (Sec. 9.2) or USDA certification (Sec. 9.3).

2.2 Purchasers *may specify* the following:

- Food defense section 9.1: Food defense system survey (FDSS) (Sec. 9.1.1), or Food defense addendum to plant systems audit (PSA) (Sec. 9.1.2), or (Sec. 9.1.2 with 9.2.1).
- Manufacturer's quality assurance (Sec. 9.2 with 9.2.1) or (Sec. 9.2 with 9.2.2).
- Packaging requirements other than commercial (Sec. 10).

3. CLASSIFICATION. The non-carbohydrate sugar substitutes shall conform to the following list which shall be specified in the solicitation, contract, or purchase order.

Types, styles, and packages.

Type I - Saccharin (1,2-benzisothiazolin-3-one-1,1-dioxide) ($C_7H_5NO_3S$) (21 Code of Federal Regulations (CFR) § 180.37)

Type II - Acesulfame potassium, also known as acesulfame K, (Potassium salt of 6-methyl-1-2-3-oxathiazine-4*(3H)*-one 2,2-dioxide) (21 CFR § 172.800)

Type III - Aspartame (1-methyl N-L-α-aspartyl-L-phenylalanine) ($C_{14}H_{18}N_2O_5$) (21CFR § 172.804)
Type IV - Sucralose (1,6-dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside) ($C_{12}H_{19}Cl_3O_8$) (21CFR § 172.831)
Type V - Neotame (N [N-(3,3-Dimethylbutyl)-L-α-aspartyl]-L-phenylalanine-1-methyl ester) (21CFR § 172.829)
Type VI - Rebaudioside A purified from the leaves of *Stevia rebaudiana* (Bertoni) and streviol glycosides
Type VII - *Siraitia grosvenorii* Swingle fruit extract (SGFE) mogrosides

Style A - Granular
Style B - Tables
Style C - Liquid
Style D - Other (*as specified by purchaser*)

Package 1 - Envelopes/packets
Package 2 - Sticks
Package 3 - Bags/boxes
Package 4 - Canister
Package 5 - Bottle
Package 6 - Other (*as specified by purchaser*)

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

- Processing guidelines (Sec. 5).
- Salient characteristics (Sec 6).
- Manufacturer's/distributor's 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. PROCESSING GUIDELINES.

5.1 Processing. The non-carbohydrate sugar substitutes shall be processed in accordance with Current Good Manufacturing Practices (21 CFR Part 110).

5.2 Food security. The non-carbohydrate sugar substitutes should be processed and transported in accordance with the Food and Drug Administration's (FDA's) *Guidance for Industry: Food*

Producers, Processors, and Transporters: Food Security Preventive Measures Guidance.[1] 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.

6. SALIENT CHARACTERISTICS.

6.1 Ingredients. All ingredients, including food grade bulking and anticaking agents, used in the preparation of the non-carbohydrate sugar substitutes shall be of Food Chemicals Codex purity or U.S. Pharmacopeia-National Formulary quality, and meet the related FDA regulations on food additives or generally recognized as safe (GRAS) requirements.

6.2 Finished Product.

6.2.1 Type I, Saccharin. The Type I, Saccharin sugar substitute shall meet the requirements of 21 CFR § 180.37.

6.2.2 Type II, Acesulfame-K. The Type II, Acesulfame-K sugar substitute shall meet the requirements of 21 CFR § 172.800.

6.2.3 Type III, Aspartame. The Type III, Aspartame sugar substitute shall meet the requirements of 21 CFR § 172.804.

6.2.4 Type IV, Sucralose. The Type IV, Sucralose sugar substitute shall meet the requirements of 21 CFR § 172.831.

6.2.5 Type V, Neotame. The Type V, Neotame sugar substitute shall meet the requirements of 21 CFR § 172.829.

6.2.6 Type VI, Stevia. The Type VI, Stevia sugar substitute shall be manufactured from the species *Stevia rebaudiana* and meet the standards, requirements, and regulations adopted by FDA for food additives, or generally recognized as safe (GRAS).

6.2.7 Type VII, SGFE mogrosides. The Type VII, SGFE mogrosides sugar substitute shall be manufactured from the species *Siraitia grosvenorii* Swingle and meet the standards,

[1] http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083075.htm

requirements, and regulations adopted by FDA for food additives, or generally recognized as safe (GRAS).

6.2.8 Sweetness equivalent. Each package type shall contain and be labeled such that the contents are equal to 2 teaspoonfuls of sugar in sweetness.

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

8. REGULATORY REQUIREMENTS. The delivered non-carbohydrate sugar substitutes shall comply with all applicable Federal and State mandatory requirements and regulations relating to the preparation, packaging, labeling, storage, distribution, and sales of the non-carbohydrate sugar substitutes in the commercial marketplace. Delivered non-carbohydrate sugar substitutes shall comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and regulations promulgated thereunder.

9. QUALITY ASSURANCE PROVISIONS. *Purchaser shall specify 9.3 or 9.4; purchaser may specify 9.1 with 9.1.1, or 9.1 with 9.1.2, 9.1.2 with 9.2.1, or 9.2 with 9.2.1, or 9.2 with 9.2.2.*

9.1 Food defense. When required in the solicitation, contract, or purchase order, a FDSS shall be conducted by USDA, Agricultural Marketing Service (AMS), Fruit and Vegetable Program (FV), Specialty Crops Inspection Division (SCI). Food defense requirements include a documented and operational food defense plan that provides for the security of a plant's production processes and includes the storage and transportation of pre-production raw materials and other ingredients and postproduction finished product. The plan shall address the following areas: (1) food security plan management; (2) outside and inside security of the production and storage facilities; (3) slaughter, when applicable, and processing, including all raw material sources; (4) shipping and receiving; (5) storage; (6) water and ice supply; (7) mail handling; (8) personnel security; and (9) transportation, shipping, and receiving.

9.1.1 FDSS. When required in the solicitation, contract, or purchase order, a FDSS shall be conducted by USDA, AMS, FV, SCI. The FDSS verifies that operators of food establishments have implemented measures to minimize the risk of tampering or other criminal actions against the food under their control. *(An AMS, FDSS verifies the participating company's adherence to the FDA's "Guidance for Industry - Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance.") For further information, see Sec. 12.1 and 12.2.2.*

9.1.2 Food defense addendum to PSA. When required in the solicitation, contract, or purchase order, a food defense addendum shall be conducted by USDA, AMS, FV, SCI auditors. This

verifies that operators of food establishments have implemented measures to minimize the risk of tampering or other criminal actions against the food under their control. *(An AMS, FDSS, PSA verifies the participating company's adherence to the FDA's "Guidance for Industry - Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance.") For further information, see Sec. 12.1 and 12.2.2.*

9.2 Manufacturer's quality assurance. When required in the solicitation, contract, or purchase order, the product manufacturer shall be required to provide evidence, by certificate, that the manufacturing plant has undertaken one of the following quality assurance measures within 12 months prior to providing a bid, or no later than 10 business days from the date of awarding of the contract. Failure to provide this documentation within the proper time frame may result in the contract being terminated for cause.

9.2.1 PSA. A PSA conducted by USDA, AMS, or other audit performed by a third party auditing service is required within 12 months prior to the date of the awarding of the contract. *(An AMS PSA verifies the manufacturer's capability to produce 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 verifies that the manufacturer has in place an internal quality assurance program.)* (Perform with food defense addendum when required.)

9.2.2 Plant survey. A plant survey conducted by USDA, AMS, or other survey performed by a third party auditing service is required within 12 months prior to the date of the awarding of the contract. *(An AMS plant survey audit 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.)*

9.3 Manufacturer's/distributor's certification. When required in the solicitation, contract, or purchase order, the manufacturer/distributor will certify that the non-carbohydrate sugar substitutes distributed meets or exceeds the requirements of this CID.

9.4 USDA certification. When required in the solicitation, contract, or purchase order that product quality and acceptability or both be determined, the SCI, FV, AMS, USDA, shall be the certifying program. SCI inspectors shall certify the quality and acceptability of the non-carbohydrate sugar substitutes in accordance with SCI procedures which include selecting random samples of the non-carbohydrate sugar substitutes, evaluating the samples for conformance with the salient characteristics of this CID and other contractual requirements, and documenting the findings on official SCI score sheets and/or certificates. In addition, when required in the solicitation, contract, or purchase order, SCI inspectors will examine the non-carbohydrate sugar substitutes for conformance to the U.S. Standards for Condition of Food Containers (7 CFR Part 42) in effect on the date of the solicitation.

10. PACKAGING. Preservation, packaging, packing, labeling, and case marking shall be commercial unless otherwise specified in the solicitation, contract, or purchase order.

11. USDA INSPECTION NOTES. When Section 9.4 is specified in the solicitation, contract, or purchase order, USDA certification shall include evaluation of the quality and condition of samples of non-carbohydrate sugar substitutes, and compliance with requirements in the following areas:

- Processing guidelines (Sec. 5)
- Salient characteristics (Sec. 6).
- Packaging requirements (Sec. 10 or as specified in the solicitation, contract, or purchase order).

12. REFERENCE NOTES.

12.1 USDA certification, FDSS, plant survey, and PSA contact. For a USDA certification, FDSS, plant survey, and PSA, contact the **Chief, Inspection Branch, SCI, FV, AMS, USDA, STOP 0240, 1400 Independence Avenue, SW, Washington, DC 20250-0240, telephone (202) 720-2482, Fax (202) 720-0393, or via E-mail: Nathaniel.Taylor@ams.usda.gov.**

12.2 Sources of documents.

12.2.1 Source of information for nongovernmental document is as follows:

Copies of the Food Chemicals Codex and U.S. Pharmacopeia may be purchased from: **United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20877-1790, telephone (800) 227-8772 or (301) 881-0666, Fax (301) 816-8148. Internet address: www.usp.org.**

12.2.2 Sources of information for governmental documents are as follows:

Applicable provisions of the U.S. Standards for Condition of Food Containers are contained in 7 CFR Part 42, 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. These documents may also be obtained free of charge on the Internet at: http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.**

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 this CID, the U.S. Standards for Condition of Food Containers (7 CFR Part 42), and beneficial comments, recommendations, additions, deletions, clarifications, etc. and any data which may improve this CID are available from and/or provided to: **Chief, Standardization Branch, SCI, FV, AMS, USDA, STOP 0240, 1400 Independence Avenue, SW, Washington, DC 20250-0240, telephone (202) 720-5021, Fax (202) 690-1527, via E-mail: CIDS@ams.usda.gov or on the Internet at: http://www.ams.usda.gov/CommercialItemDescription.**

Copies of this CID are also available online at: **ASSIST Online (https://assist.dla.mil) or ASSIST Quick Search (https://assist.dla.mil/quicksearch) or from the Standardization Documents Order Desk, Defense Logistics Agency (DLA) Document Services, Building 4D, 700 Robbins Avenue, Philadelphia, PA 19111-5094.**

MILITARY INTERESTS:

Military Coordinating Activity

Army - GL

Custodians

Army - GL
Navy - SA
Air Force - 35

Review Activities

Army - MD, QM
Navy - MC
DLA - SS

CIVIL AGENCY COORDINATING ACTIVITIES:

DOJ - BOP
HHS - NIH, IHS, FDA
USDA - FV
VA - OSS

PREPARING ACTIVITY:

USDA - FV