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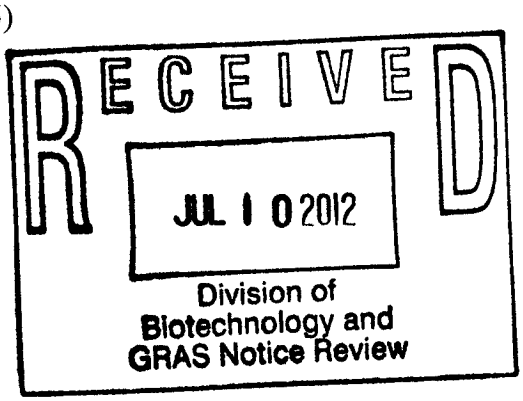
July 9, 2012

Via Overnight Mail

Antonia Mattia, Ph.D., Director
Division of Biotechnology and GRAS Notice Review (HFS-225)
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740



Re: GRAS Notification for Resistant Dextrin

Dear Dr. Mattia:

We respectfully submit the attached GRAS Notification on behalf of our client Roquette Freres for Resistant Dextrin (Nutriose® 6 and Nutriose® 10) for use as a bulking agent and a dietary fiber ingredient in food (excluding meat products, poultry products and infant formula). The attached GRAS Notification provides a review of the information related to the intended uses and manufacturing and safety of the ingredient. We have included three (3) hard copies of the GRAS Notification and the Appendices including the GRAS Expert Panel Opinion.

Roquette Freres has determined that Resistant Dextrin is generally recognized as safe (GRAS) based on scientific procedures in accordance with 21 C.F.R. § 170.30(b) and conforms to the guidance issued by the Food and Drug Administration (FDA) under *proposed* 21 C.F.R. § 170.36, 62 Fed. Reg. 18938 (Apr. 17, 1997). The GRAS determination has also been evaluated by experts qualified by scientific training and experience to assess the safety of Resistant Dextrin under the conditions of its intended use in food. Therefore, the use of Resistant Dextrin in food as described in this GRAS Notification is exempt from the requirement of premarket approval as set forth in the Federal Food, Drug, and Cosmetic Act.

The analytical data, published studies, and information that are the basis for this GRAS determination are available for FDA review and copying at reasonable times at Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001 or will be sent to FDA upon request.

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We look forward to the Agency's review of this submission and would be happy to provide the Agency with any information they need to complete their review.

Sincerely,

(b) (6)

Melvin S. Drozen

Enclosures

GRAS Notification for Roquette's

Resistant Dextrin

Prepared for:

U.S. Food and Drug Administration
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

Prepared by:

Keller and Heckman LLP
1001 G Street, NW
Suite 500W
Washington, DC 20001

Table of Contents

A. Introduction

Keller and Heckman LLP submits the enclosed information on behalf of our client Roquette Freres (Roquette) in support of this notification that Resistant Dextrin is Generally Recognized as Safe (GRAS) for use in food as a bulking agent and as a dietary fiber ingredient.

Roquette has determined that Resistant Dextrin is GRAS based on scientific procedures in accordance with 21 C.F.R. § 170.30(b) and conforms to the guidance issued by the Food and Drug Administration (FDA) under *proposed* 21 C.F.R. §170.36, 62 Fed. Reg. 18938 (Apr. 17, 1997). The GRAS determination has also been evaluated by experts qualified by scientific training and experience to assess the safety of Resistant Dextrin under the conditions of its intended use in food. The analytical data, published studies, and information that are the basis for this GRAS determination are available for FDA review and copying at reasonable times at Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001 or will be sent to FDA upon request.

We submit information in the following areas:

- Identity of the substance.
- The production of Resistant Dextrin.
- Specifications and equivalence of Resistant Dextrin derived from corn and wheat.
- Technological properties of Resistant Dextrin.
- Intended uses and an estimation of consumption of Resistant Dextrin.
- Relevant safety data on Resistant Dextrin.
- Laxation potential.
- External panel reviewers' evaluation and conclusion that Resistant Dextrin is GRAS for its intended uses.

It is our expectation that FDA will concur that the information presented fully supports the determination that Resistant Dextrin as produced by Roquette is GRAS for use as a bulking agent and as a dietary fiber ingredient in food (excluding meat products, poultry products, and infant formula).

B. Administrative Information

1. Claim Regarding GRAS Status

Keller and Heckman LLP on behalf of Roquette hereby notifies the agency of its determination that Resistant Dextrin is GRAS based on scientific procedures for use in food as a bulking agent and as a dietary fiber ingredient.

2. Name and Address of the Notifier

Roquette Freres
Batiment Alpha 3
Lestrem 62080
FRANCE

All communications on this matter are to be sent to Counsel for the Notifier

Melvin S. Drozen
1001 G Street, NW
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Washington, DC 20001
Telephone: (202) 434-4222
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3. Common or Usual Name of the Subject Substance

Resistant dextrin[1]
Synonyms: dextrin, dextrin (fiber), dextrin (dietary fiber), dextrin (soluble fiber), dextrin (soluble dietary fiber), resistant dextrin (fiber), resistant dextrin (dietary fiber), resistant dextrin (soluble fiber), and resistant dextrin (soluble dietary fiber), soluble corn fiber, soluble wheat fiber

4. Intended Use and Self-Limiting Levels of Use

Resistant Dextrin is proposed for use in food as a bulking agent and as a dietary fiber ingredient. The use of Resistant Dextrin as a food ingredient is limited by the level that can technically be added to a given food without jeopardizing its quality and consumer acceptability. Further, use is limited by the cost of the Resistant Dextrin ingredient; food manufacturers will generally only use the amount of Resistant Dextrin necessary for it to contribute a meaningful amount of fiber per serving of the finished food product.

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[1] Customers will be advised that when NUTRIOSE® is derived from wheat, the term "wheat" must be used as part of the ingredient listing for allergen labeling purposes.

Roquette had Exponent generate a consumption estimate for Resistant Dextrin based on its use in sixteen food categories at three to nine grams per serving. The sixteen food categories were selected as the most common use applications for this ingredient. The U.S. Per Capita mean intake from these selected food categories is 17.1 g/day and the corresponding 90th percentile intake is 32.5 g/day. See further discussion in Section E, and Appendix I.

C. Criteria for GRAS Status

Roquette has obtained confirmation of the GRAS status of Resistant Dextrin from a panel of experts that are qualified by scientific training and expertise to evaluate the safety of food ingredients. It is respectfully submitted that this Notification establishes GRAS status for Resistant Dextrin for use in food based on: (1) the published safety data on dextrin which is used in the manufacture of Resistant Dextrin; (2) the published safety data on Roquette's Resistant Dextrin; (3) the published safety studies of polydextrose, which is a glucose polymer that has similar atypic bondings as those found in Roquette's Resistant Dextrin; and (4) the fact that the estimated daily intake (EDI) for Roquette's Resistant Dextrin, based on the intended uses of the product in food, is similar to the safe level established for polydextrose.

D. Detailed Information about the Identity of the Notified Substance

1. Name and Other Identities

Chemical Name:	Dextrin
CAS Registry Number:	9004-53-9
Empirical Formula:	(C6H6O6)n
Structural Formula:	See Figure 1-B

NUTRIOSE® 6 and NUTRIOSE® 10 are Roquette's trade names for substantially chemically equivalent Resistant Dextrins. NUTRIOSE® 10 contains higher levels of mono- and di-saccharides than NUTRIOSE® 6 (See Table 1), but the composition of the higher molecular weight oligomers is the same in both versions. As a result, there is a slight difference in the average molecular weight and degree of polymerization that produces slightly different physical properties of commercial value. We refer generally to NUTRIOSE® 6 and NUTRIOSE® 10 as Resistant Dextrin except when a specific product is the subject of a study.

2. Chemical and Physical Properties

Dextrins are partially hydrolyzed starches (glucose polymers) produced by heating starch in the presence of small amounts of food-grade acid. Dextrinization results in a drastically reduced molecular weight and the introduction of new glucoside linkages. Unlike starches and maltodextrins which contain only "digestible" α- (1,4) and α- (1,6) glucosidic linkages, dextrins also contain "nondigestible" (1,2) and (1,3)- glucosidic linkages. These nondigestible linkages are not hydrolyzed by human digestive enzymes. As a result, a portion of the dextrin is not digested in the upper part of the gastro-intestinal tract and is not directly available as such for

energy utilization. However, a portion of the nondigested material is hydrolyzed by bacterial flora in the colon and the resulting free fatty acids are utilized for energy. The occurrence of nondigestible linkages is a well-known characteristic of dextrins as well as polydextrose.[2]

Roquette's Resistant Dextrin is a specialty dextrin that is produced using a highly controlled process of starch dextrinization followed by enzymatic treatment and column chromatography. This process produces a highly indigestible, soluble dextrin, with a higher fiber content and a desired narrower molecular weight distribution. (See Table 1). Depending on the stage of the chromatographic collection process, either NUTRIOSE® 6 (M_w = 4000-6000) or NUTRIOSE® 10 (M_w = 3500-4500) is obtained. These are compared with starch, two traditional dextrins, and polydextrose in Table 1.

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[2] Polydextrose is a glucose polymer like dextrin, but is manufactured differently. See Section F.4.

TABLE 1

Compositional Comparison Between Roquette's Resistant Dextrin and Other Products

	Starch	Dextrins[3]	NUTRIOSE® 6	NUTRIOSE® 10	Polydextrose[4]
Reducing Sugar (% on dry basis)	**0**	**4-10**	**2.0-5.0**	**8.0-12.0**	-
Degree of Polymerization	62 x 10^3	15-30	12-25	4-10	12
M_n (Number Avg Mol Wt)	~10^7	2400-5000	2000-4000	800-1500	800
M_w (Weight Avg Mol Wt)	~10^7	9000-25000	4000-6000	3500-4500	2000
Polydispersity (M_w/M_n)	-	3-6	1.5-2.5	3-4.5	2.5
Total Dietary Fibers %[5]	0	20-45%	Average 85%	Average 70%	90
% Glucosidic linkages					
(1,4)	95	69-85	50	50	26
(1,6)	5	9-21	30	30	40
(1,2)	0	4-6	10	10	18
(1,3)	0	2-4	10	10	16

The average degree of polymerization of NUTRIOSE® 6 is 12-25 and that of NUTRIOSE® 10 is 4-10. Table 1 also compares the glycosidic links found in NUTRIOSE® 6 and NUTRIOSE® 10 with those in starch, dextrin, and polydextrose. Please note that the glycosidic linkages in NUTRIOSE® 6 and NUTRIOSE® 10 are the same because the percent linkages are based on the fiber portion and not the entire fraction, fiber and sugars. The two

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[3] Dextrin composition based on specifications for TACKIDEX C070 and CLEARGUM® TA 90, which are tradenames for dextrins produced by Roquette.

[4] S. A. S. Craig, J. F. Holden, J. P. Troup, M. H. Auerbach, and H. I. Frier. (1998) Polydextrose as Soluble Fiber: Physiological and Analytical Aspects. Cultor Food Science, Ardsley, NY. American Association of Cereal Chemists, Inc.

[5] The total fiber content is determined by the following methods: (1) Dextrin: AOAC Method 2001.03; (2) NUTRIOSE® 6 and NUTRIOSE® 10: AOAC Method 2001.03; (3) Polydextrose: AOAC Method 2000.11.

structural formulas in Figure 1.A. and 1.B. illustrate the difference in bonding between starch and Resistant Dextrin.

FIGURE 1.A.

Structural Formula for Starch

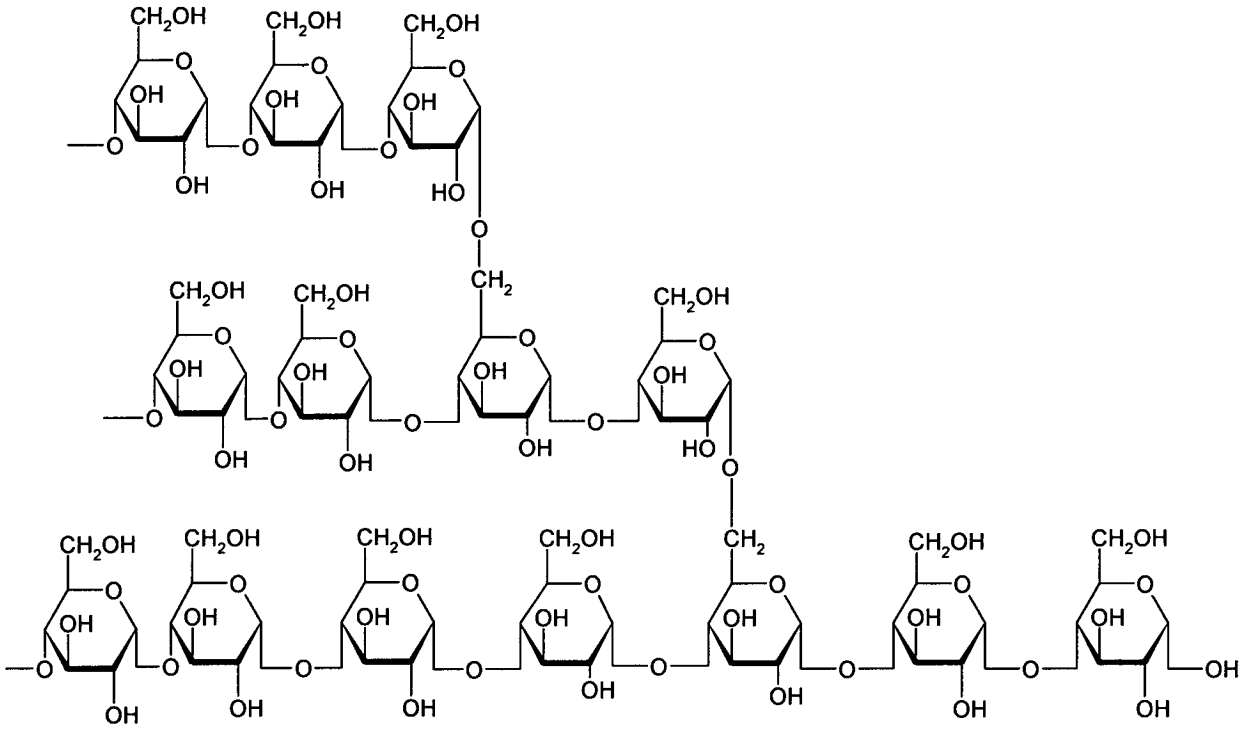
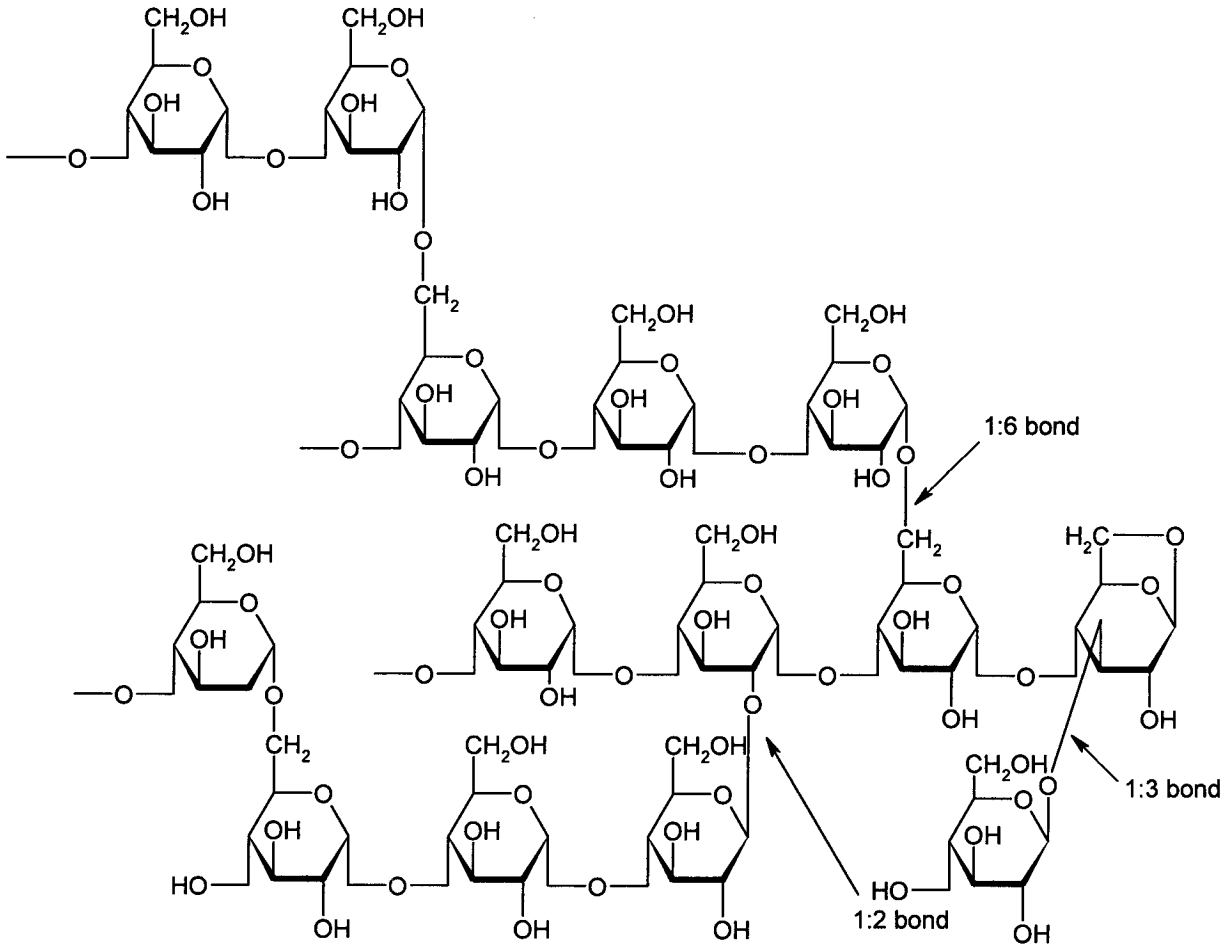


FIGURE 1.B.

Structural Formula for Roquette's Resistant Dextrin



Roquette's Resistant Dextrins also have a high dietary fiber content due to the "non-digestible" α- and β- linkages, which is a well-known characteristic of dextrins. Using AOAC Method 2001.3, the average level of dietary fiber in NUTRIOSE® 6 is 85% and in NUTRIOSE® 10 is 70%.

3. Manufacture

a. Production of Resistant Dextrin

The manufacturing process for Resistant Dextrin begins with the production of traditional dextrin from corn or wheat starches. Dextrinization is the process of dry roasting acidified starch from any of several grain or root-based sources. The products obtained are referred to as dextrins or, more accurately, as pyrodextrins. Depending on the reaction conditions (*e.g.*, acidity, moisture, temperature, and length of treatment), dextrinization produces a range of products that vary in average molecular weight, color, viscosity, cold-water solubility, reducing sugar content, and stability. Depending on the conditions, repolymerization may occur in addition to the

hydrolysis.[6] Repolymerization generally creates new glycosidic bonds in addition to the typical starch α-1,4 and α-1,6 linkages.[7] These include both linear and branched, nondigestible linkages, *e.g.*, linear and/or branched α-1,2 and/or β-1,2; β-1,4; α-1,3 and/or β-1,3 linkages; and β-1,6 linkages. In dextrin, the proportion of 1,6-linkages rises to at least 10% as a result of the higher susceptibility of 1,4-linkages to acid treatment and because of transglycosylation due to the dextrinization process.

The dextrin used as the starting material to make Resistant Dextrin is a yellow dextrin with a molecular weight (M_n) from 3000 to 10,000 (ICUMSA-International Commission for Uniform Methods of Sugar Analysis). Dextrinization takes place under high temperatures (160°C to 200°C) and short time (maximum 1 minute). The Food Chemicals Codex (FCC) describes food grade dextrin (CAS 9004-59-3) as follows:

> "Dextrin occurs as free-flowing, white, yellow, or brown powders and consist chiefly of polygonal, rounded, or oblong or truncated granules. Dextrin is partially hydrolyzed starch converted by heat alone, or by heating in the presence of suitable food-grade acids and buffers, from any of several grain- or root-based unmodified native starches (*e.g.*, corn, waxy maize, high amylose maize, milo, waxy milo, potato, arrowroot, wheat, rice, tapioca, sago, etc.). Dextrin is partially to completely soluble in water."[8]

In the next step of the Resistant Dextrin manufacturing process, dextrin is partially hydrolyzed under very mild conditions using food grade α-amylase derived from *Bacillus licheniformis* or other safe and suitable enzymes because it allows for a better filtration throughout the remaining steps of the process.[9] The resulting dextrin is purified by activated

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[6] For example, white dextrin is produced by exposures of 3-7 hours, to temperatures of 110-130 °C, and the product is formed mainly by hydrolysis. Yellow dextrin is roasted at 135-160 °C for 8-14 hours and is formed by hydrolysis and repolymerization. Finally, British Gum dextrin is roasted to higher temperatures, 150-180 °C, for longer periods, 10-24 hours, and involves mainly repolymerization. See Pizzi, A., Mittal, K. L., Handbook of Adhesive Technology, Second Edition, p. 503 (2003).

[7] In the linear Fischer representations, the structure with the anomeric hydroxyl group directed to the same side as the hydroxyl group at the highest numbered asymmetric carbon atom (C-5 for hexoses) is termed the α form and that with the opposite orientation (–OH at C-1 and C-5 going in different directions) is termed the β form.

[8] Food Chemicals Codex, 7th Edition (2010), Dextrin, pp. 280-282.

[9] Alpha-amylase derived from *B. licheniformis* is safe and suitable for use here for several reasons. First, mixed carbohydrase and protease enzyme product derived from *B. licheniformis* is affirmed as GRAS in 21 C.F.R. §184.1027. Further, several genetically modified forms of *B. licheniformis* have been the subject of GRAS Notifications (GRN 000022, 000024 and 000072). Finally, the preamble to the GRAS affirmation regulation for maltodextrin recognizes the use of amylases in the production process. See 21 C.F.R. §184.1444 and 60 Fed. Reg. 48890 at 48891 (Sep. 21, 1995).

carbon treatment and the use of cationic and anionic resins. This step removes most mineral and organic impurities. The majority of the protein is removed by the cationic and anionic resins. The protein content is reduced from about 1% in the dextrin to less than or equal to 0.3% in Resistant Dextrin.[10]

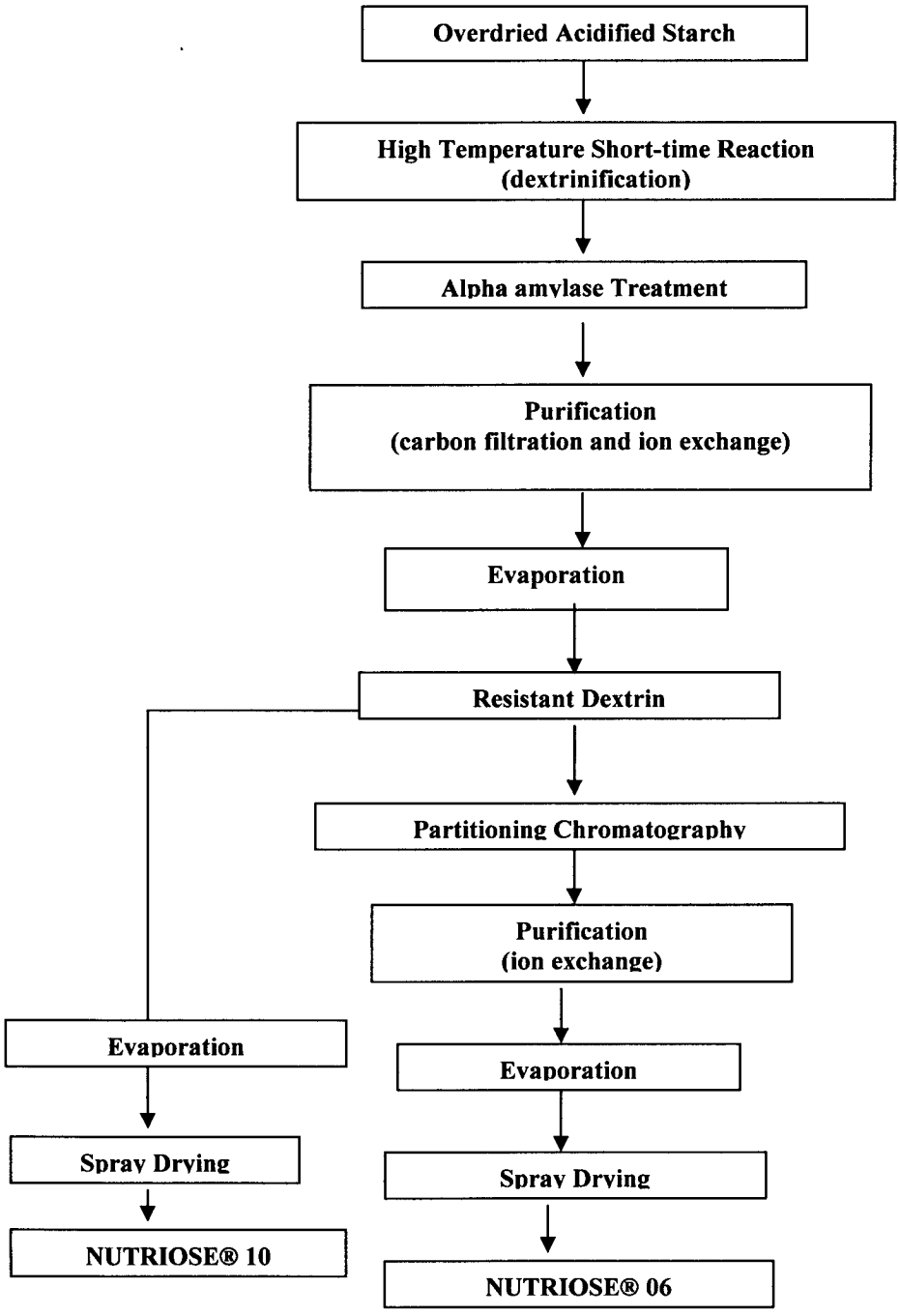
NUTRIOSE® 6 is the Resistant Dextrin that goes through chromatographic separation (partitioning) to remove the sugars, i.e., lower molecular weight fractions DP1 and DP2 saccharides, to create a product with higher molecular weight sugars. The partitioning is accomplished by the use of a macroporous cationic resin, and is followed by further purification (ion exchange) and spray drying to make NUTRIOSE® 6. NUTRIOSE® 10 is the Resistant Dextrin that is further evaporated and then spray dried.

The difference between NUTRIOSE® 6 and NUTRIOSE® 10 is the presence or absence of sugars. The production process of NUTRIOSE® 6 involves partitioning chromatography and additional purification to remove any additional impurities that may have resulted from the chromatographic process. This purification step is typical of processes that utilize chromatography.

A flow chart for the manufacture of Roquette's Resistant Dextrin is shown below in Figure 2.

FIGURE 2

Resistant Dextrin General Manufacturing Diagram



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[10] See Food Chemicals Codex 7th Edition specification for Dextrin where protein is NMT 1.0% (p. 282). See Table 3 for protein content in Resistant Dextrin.

b. Equivalence of Corn or Wheat Derived Resistant Dextrin

The standard wheat or corn starches used in the production of Resistant Dextrin have similar ratios of amylose (25%) and amylopectin (75%). The minor differences that may exist between the starches in granule size and molecular weight are equalized during the dextrinization process (transglycosylation reaction), which converts both starches to a mixture of glucose polymers. The average degree of polymerization of Resistant Dextrin from each starch is approximately 12-25 as compared to several thousand for starch. The distribution of glycosidic linkages is essentially identical in the NUTRIOSE® 6 Resistant Dextrin and NUTRIOSE® 10 Resistant Dextrin made from either starch (See Table 1). The data below shows the virtually identical polymeric distribution of the NUTRIOSE® products from a total of six production batches (three for NUTRIOSE® FB and three for NUTRIOSE® FM).

TABLE 2
Equivalence of NUTRIOSE® FM (derived from corn) and NUTRIOSE® FB (derived from wheat)[11]

	NUTRIOSE® FM 06				NUTRIOSE® FB 06				Results
	Target value	Batch E1952	Batch E8968	Batch E3207	Target value	Batch E6098	Batch E6186	Batch E5107	
Number Avg Molecular Weight g/mole[12]	2500-2900	2515	2705	2815	2500-2900	2580	2810	2485	No significant difference
Weight Avg Molecular Weight g/mole	4700-5300	5075	5130	5045	4700-5300	4765	5020	4745	No significant difference
Polydispersity	1.5-2.5	2.02	1.87	1.79	1.5-2.5	1.84	1.79	1.90	No significant difference
Degree of polymerization	16-17	16	17	17	16-17	16	17	16	No significant difference
% Glucosidic linkages for (1,4) (1,6) (1,2) (1,3)	Ratio of (1.4) 50 % (1.6) 30 % (1.3) 10 % (1.2) 10 %	45.7 31.3 11.6 11.3	43.0 33.0 12.4 11.7	50.6 35.3 6.3 7.9	Ratio of (1.4) 50 % (1.6) 30 % (1.3) 10 % (1.2) 10 %	50.1 30.4 10.0 9.5	49.3 30.0 11.1 9.7	46.1 32.5 10.2 11.2	No difference

[11] We only evaluate the equivalence of NUTRIOSE® FM 6 derived from corn and NUTRIOSE® FB 6 derived from wheat and not NUTRIOSE® 10 because the only difference between NUTRIOSE® 6 and NUTRIOSE® 10 is the degree of processing, which will have no effect on the equivalence of the substances based on starting raw material (corn or wheat).

[12] The molecular weight information reported in Table 2 for NUTRIOSE® 6 is a target value and is narrower than the range reported in Table 1.

Further support for the equivalence between NUTRIOSE® derived from wheat and corn can be found in the French Food Safety Agency, Agence Francaise de Securite Sanitaire Des Aliments (AFSSA) Opinion regarding NUTRIOSE®.[13] In this opinion, the AFSSA acknowledges that the Resistant Dextrin is produced from corn and wheat and treats the Resistant Dextrin obtained from either source as equivalent-

> "The product manufactured by the Petitioner is a carbohydrate polymer of vegetable origin having a DP ≥3 that is chemically converted. It is available in two forms which are obtained from starch from two distinct vegetable sources (wheat or maize)."

c. Specifications

Production specifications for Resistant Dextrin (NUTRIOSE® 6 and NUTRIOSE® 10) are given in Table 3.[14] Again, NUTRIOSE® 10, consisting of a lower molecular weight fraction has more reducing sugars and mono-and disaccharides than NUTRIOSE® 6, but is otherwise identical as discussed further in **Section F.2.**

TABLE 3

Production Specifications for Resistant Dextrins

	Resistant Dextrin NUTRIOSE® 6	Resistant Dextrin NUTRIOSE® 10	Method
Chemical Analysis			
Loss on Drying	≤ 5%	≤ 5%	Internal Company Method MCL 209A (*European Pharmacopeia reference*)
Monosaccharides *plus* Disaccharides	≤ 0.5%	≤ 15%	Internal Company Method MCL 190Y (*High Performance Liquid Chromatography validated method*)
Ash	≤ 0.5%	≤ 0.5%	Internal Company Method MCL 010A (*Total ash validate method*)
Protein content (N 6.25)	≤ 0.3%	≤ 0.3%	Internal Company Method MCL 030H (*Dumas validated method reference NF V 18-120, French Association of Standardization*)

[13] French Food Safety Agency AFSSA, Opinion of the French Food Safety Agency relating to the evaluation of the classification of a dextrin as soluble dietary fibre and of the evidence to support the associated nutrition claims (July 30, 2007).

[14] NUTRIOSE® 6 and NUTRIOSE® 10 meet the Dextrin FCC specification except for the iodine identification test. In addition, to meeting the Dextrin FCC specification for reducing sugars, loss on drying, protein and ash, NUTRIOSE® 6 and NUTRIOSE® 10 also meet the Dextrin FCC specifications for chloride (NMT 0.2%), lead (NMT 1 mg/kg), sulfur dioxide (NMT 0.005%), and crude fat (NMT 1.0%)."

TABLE 3 Production Specifications for Resistant Dextrins			
	Resistant Dextrin NUTRIOSE® 6	**Resistant Dextrin NUTRIOSE® 10**	**Method**
Total Dietary Fiber	82-88%	65-75%	Internal Company Method MCL 1457 (*Enzymatic Gravimetric Method and Liquid Chromatographic Determination validated method AOAC 2001.03*)
Particle size : Residue on 500 microns Residue on 40 microns	 <10% >90%	 <5% >90%	Internal Company Method MCL 110A (*ALPINE air jet sieve validated method*)
Microbiological			
Total plate count	≤ 1000 cfu/g	≤ 1000 cfu/g	Internal Company Method MMC 2002-A (*colony count technique standard method NF EN ISO 4833*)
Yeasts	≤50 cfu/g	≤50 cfu/g	Internal Company Method MMC 2003-A (*colony count technique standard method NF V08-059, French Association of Standardization*)
Moulds	≤ 50 cfu/g	≤ 50 cfu/g	Internal Company Method MMC 2003-A (*colony count technique standard method NF V08-059, French Association of Standardization*)
Escherichia coli	Absence in 25 g	Absence in 25 g	Internal Company Method MMC 2009-C (*enrichment method, European Pharmacopeia reference*)
Salmonella	Absence in 25 g	Absence in 25 g	Internal Company Method MMC 2010-E (*ELISA immunocapture method validated with ISO 6579*)

d. Data on Representative Lots

Ten production lots, five of NUTRIOSE® 6 and five of NUTRIOSE® 10, were analyzed with respect to the different parameters indicated in the specifications for Resistant Dextrin NUTRIOSE® 6 and NUTRIOSE® 10. The corresponding data are presented below in Tables 4 and 5. The results of the analyses indicate consistency in production and compliance with relevant specifications.

TABLE 4
Analysis of representative lots of NUTRIOSE® 6

	Specification	Batch E8981	Batch E8929	Batch E8930	Batch E8931	Batch E8932
Loss on Drying (%)	≤ 5	3.2	3.7	3.4	3.5	3.5
Monosaccharides plus Disaccharides (%)	≤ 0.5	0.2	0.3	0.2	0.2	0.2
Ash (%)	≤ 0.5	< 0.10	< 0.10	< 0.10	< 0.10	< 0.10
Protein Content (N 6.25) (%)	≤ 0.3	0.08	0.03	0.04	0.04	0.04
Total Dietary Fiber (%)	82-88	86	86	86	86	86
Particle Size: -Residue on 500 microns (%) -Residue on 40 microns (%)	<10 >90	0.2 92	0.6 95	0.2 94	0.2 91	0.2 91
Total Plate Count	≤ 1000 cfu/g	5 /g	< 10/g	5/g	5/g	< 10/ g
E. Coli	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g
Salmonella	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g
Moulds	≤ 50 cfu/g	< 5/ g	< 5 /g	< 5 /g	< 5 /g	< 5 /g
Yeasts	≤ 50 cfu/g	< 5/ g	< 5 /g	< 5/ g	< 5 /g	< 5/ g

TABLE 5
Analysis of representative lots of NUTRIOSE® 10

	Specification	Batch E9440	Batch E2047	Batch E2048	Batch E8338	Batch E8636
Loss on Drying (%)	≤ 5	3.2	3.2	3.2	2.6	2.8
Monosaccharides plus Disaccharides (%)	≤ 15	5.0	10.0	9.6	4.6	6.9
Ash (%)	≤ 0.5	< 0.10	< 0.10	< 0.10	< 0.10	< 0.10
Protein Content (N 6.25) (%)	≤ 0.3	0.05	0.06	0.06	0.08	0.05
Total Dietary Fiber (%)	65-75	73	73	74	71	75
Particle Size: -Residue on 500 microns (%) -Residue on 40 microns (%)	<5 >90	0.1 94	0.1 95	0.1 93	< 0.1 92	< 0.1 91
Total Plate Count	≤ 1000 cfu/g	< 10 g	< 10 g	5 g	< 10 g	< 10 g
E. Coli	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g
Salmonella	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g	Absence in 25g
Moulds	≤ 50 cfu/g	< 5 g	< 5 g	< 5 g	< 5 g	< 5 g
Yeasts	≤ 50 cfu/g	< 5 g	< 5 g	< 5 g	< 5 g	< 5 g

e. Contaminants

Microbiological controls are incorporated in the Resistant Dextrin manufacturing process to ensure that the substance is free of pathogenic or other objectionable organisms or unwanted microbial metabolites, and that Resistant Dextrin is otherwise suitable for its intended use. The product is currently produced in Europe in compliance with the European hygiene legislation (Regulation 852/2004 EC and Regulation 178/2002 EC), which includes application of Hazard Analysis Critical Control Points (HACCP). The production methods are consistent with current U.S. good manufacturing practices (cGMP) at 21 C.F.R. Part 110.

The starting materials, corn starch or wheat starch, have been tested for the potential presence of over 250 different pesticide residues from pesticides commonly used in a broad range of crops in the U.S. and Europe. None of these pesticides were detected in any of the samples (below limits of detection).

The Resistant Dextrin was also tested for mycotoxin contaminants and none were detected (below limits of detection). Table 6 below lists the results of analyses for mycotoxins.

TABLE 6
Maximum Mycotoxin Levels in Resistant Dextrin

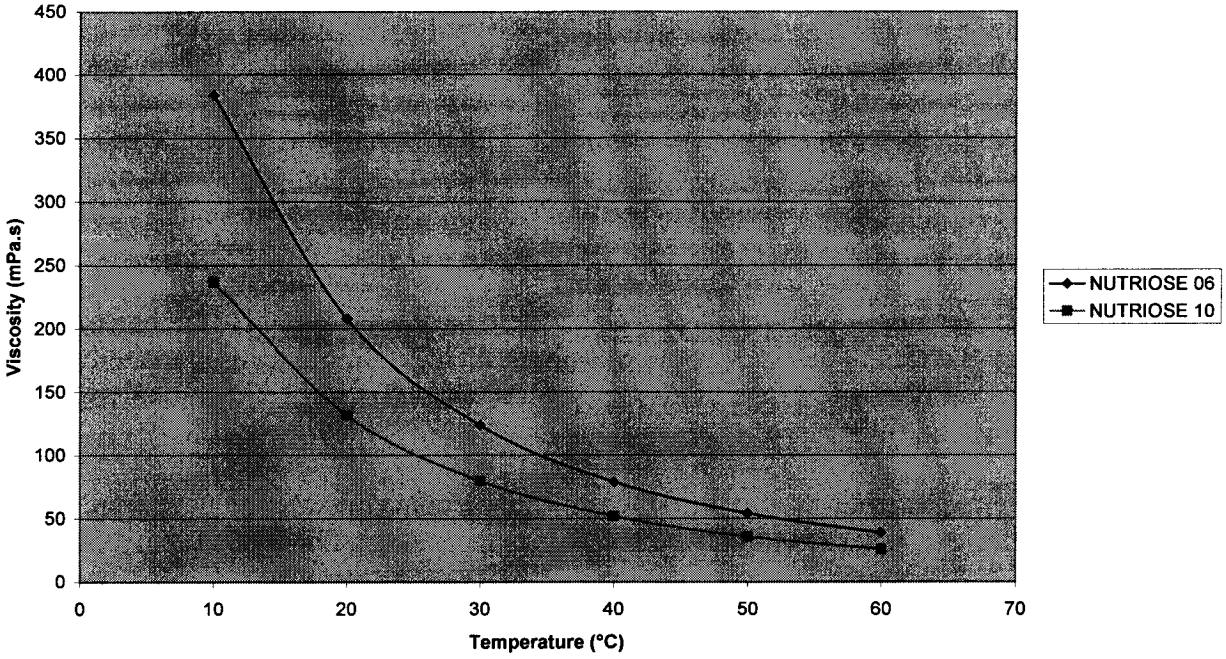
Mycotoxins	Below Limit of Detection (Maximum Level)	Method
Aflatoxines B1	0.02µg/kg	Chromotography
Aflatoxines total	0.08µg/kg	Chromotography
Ochratoxin A	0.2µg/kg	Chromotography
Fumonisine B1	30 µg/kg	Chromotography
Zearalenone	1µg/kg	Chromotography
DON	30 µg/kg	Chromotography

f. Technological Properties

Roquette's Resistant Dextrin is produced in a spray dry form which has three advantages: it is free flowing, has quick dispersion and rapid dissolution. Resistant Dextrin has a high solubility and a low viscosity that permits good production conditions for finished products on industrial lines. See Figure 3 below.

FIGURE 3

Viscosity of NUTRIOSE solutions at 50 % DS



The chemical structure of Resistant Dextrin provides for its very good stability under different conditions of pH and temperature. The stability is a result of the production process, the elimination of remaining low molecular weight oligomers and the presence of atypic bondings. This is essential for maintaining the fiber content in acidic foods such as soft drinks during their entire shelf life or for pasteurized/sterilized products. Roquette has generated stability data for the Resistant Dextrins and the shelf-life is 24 months.

E. Estimated Consumption of Resistant Dextrin from Proposed Food Uses

Resistant dextrin is proposed for use in food as a bulking agent and as a dietary fiber ingredient. The use of Resistant Dextrin as a food ingredient is limited by the level that can technically be added to a given food without jeopardizing its quality and consumer acceptability. Further, use is limited by the cost of the Resistant Dextrin ingredient; food manufacturers will generally only use the amount of Resistant Dextrin necessary for it to contribute a meaningful amount of fiber per serving of the finished food product.

Resistant dextrin will potentially be used in the following food categories at approximately three to nine grams per serving: (1) baked goods; (2) beverages liquid non-dairy; (3) cereals and granola bars; (4) condiments and dressings; (5) confections; (6) dairy beverages; (7) dairy non-beverages; (8) frozen desserts; (9) gravies and sauces; (10) meal replacements; (11) pasta and grain products; (12) prepared meals and soups; (13) processed fruits; (14) shelf-stable desserts; (15) snacks and crackers; and (16) dry beverage powder. These 16 food categories were

selected as the most common potential use example applications for this ingredient in order to generate the most accurate consumption data.

Roquette had Exponent generate a consumption estimate for Resistant Dextrin based on its use in these sixteen food categories. Exponent calculated the estimated daily intake (EDI) of Resistant Dextrin using food consumption data for the sixteen food categories from the National Health and Nutrition Examination Surveys (NHANES) conducted in 2003-2004 and 2005-2006 (NCHS 2007, 2008).[15] Details regarding the use of the consumption databases and methods of calculation are described in the Exponent Report, which is available as **Appendix I.**

The U.S. Per Capita mean intake from all the selected food categories is 17.1 g/day and the corresponding 90th percentile intake is 32.5 g/day. FDA has established a daily reference value (DRV) for fiber of 25 grams per day. We do not realistically expect that the actual consumption of foods containing Resistant Dextrin will result or even approach a daily consumption of the DRV for fiber. Only the inherent conservatism in the typical intake calculations suggests the possibility of exceeding the DRV at the 90th percentile.

Nearly all people in the total U.S. population and each of the selected subpopulations reported eating at least one food proposed for Resistant Dextrin (% users are all > 98%). As a result the mean and 90th percentile per user intakes are close to their per capita values; the mean per user = 17.4 g/day and 90th percentile per user = 32.6 g/day. The per user 90th percentile for the various age and gender subgroups ranged from 20.2 g/day (children 1 to 6years) to 39.3 g/ day (males 20+ years). See Table 1 in the Exponent Report.

The daily intakes in g/day for the individual food categories and for all food categories combined are given in Table 7. Non-dairy beverages, cereals and granola bars, baked goods, condiments and dressings, and snacks and crackers were the greatest contributors to the overall resistant dextrin intake. These 5 categories accounted for 80% of the total *per capita* U.S. population mean intake.

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[15] Exponent Report (2011), Estimated Daily Intake of Resistant Dextrin from Selected Foods in the U.S., Center for Chemical Regulation and Food Safety. See Appendix I.

TABLE 7 U.S. Per Capita and Per User Estimated Daily Intake for Resistant Dextrin				
Food Group	**Per Capita (g/day)**		**Per User (g/day)**	
	Mean	**90th Percentile**	**Mean**	**90th Percentile**
Baked Goods	1.8	4.6	2.8	5.4
Beverages liquid-non dairy	6.9	18.0	9.7	21.7
Cereals and Granola Bars	3.1	8.9	6.0	11.4
Condiments and Dressings	1.4	4.2	2.8	6.3
Confections	0.01	0	1.0	2.9
Dairy Beverage	0.5	1.5	3.2	6.9
Dairy Non-beverage	0.5	1.7	1.9	3.8
Frozen Desserts	0.2	0	1.9	3.7
Gravies and Sauces	0.6	2.1	1.7	3.5
Meal Replacements	0.04	0	3.2	6.4*
Pasta and Grain Products	0.1	0	1.7	3.1
Prepared Meals and Soups	0.3	0.8	2.2	4.1
Processed Fruit	0.3	0.5	2.3	4.9
Shelf-stable Desserts	0.05	0	1.9	3.0
Snacks and Crackers	1.0	3.1	2.7	6.2
Dry Beverage Powder	0.5	1.5	3.9	7.9
All Foods Combined	**17.1**	**32.5**	**17.4**	**32.6**

- Estimates at the 90th percentile are statistically unreliable due to insufficient sample size.
- Estimates are for individuals 2+ years and older.

F. Safety of Use in Foods

Resistant Dextrin is a specialty dextrin that is produced by a controlled process that consistently produces a product within the stated specifications. The process begins with starch dextrinization followed by enzymatic hydrolysis and chromatographic separation. In **Section F.1** below, the safety of dextrin *per se* is reviewed. Resistant Dextrin is a refined dextrin and the safety of the starting material, unrefined dextrin, is highly relevant. **Section F.2** addresses the safety of Resistant Dextrin itself and discusses the results of a published 90-day study in rats and other studies on the article of commerce. **Section F.3** discusses the need for allergen labeling for the Resistant Dextrin that is derived from wheat. The safety of polydextrose, which is based on published safety studies and is substantially similar to Resistant Dextrin, is reviewed in **Section F.4.** A discussion of the relationship between laxation and Resistant Dextrin is discussed in **Section F.5**. Finally, as discussed in **Section F.6**, a study on energy value of Resistant Dextrin demonstrates that Resistant Dextrin has a positive effect on mineral absorption and retention.

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1. Safety of Dextrin

Dextrins are one commercial entity in a family of unmodified starch and starch hydrolysis products that include (in order of decreasing molecular weight) starch, dextrins, maltodextrins, glucose syrups, and, finally, glucose (dextrose).[16] Traditional dextrins are derived from food starches that have been hydrolyzed by the action of dry heat in the presence of acid.[17] Dextrins are usually composed of a range of polymers and glucose. A typical starch polymer might have a molecular weight of 10^7 grams/mole as determined by size exclusion chromatography (SEC).

At the request of FDA, the safety of dextrin was reviewed by the Select Committee on GRAS Substances (SCOGS) in the early 1970's and the report was issued in 1975.[18] Based on recommendations from this panel, and the FDA's own review of the available safety data, a final rule affirming the GRAS status of dextrin for a variety of food uses was issued by the Agency in 1983 at 21 C.F.R.§ 184.1277.

The SCOGS panel discussed seven papers on the nutritional and physiological effects observed in animals after eating high levels of dextrin and other carbohydrates. These studies were generally from 2-12 weeks long at levels of 40 – 80 g/kg bw/day and resulted only in modest reductions on growth and enlarged ceca, both reportedly due to the partial indigestibility of dextrin. These studies were not designed as toxicity studies.

In an 18-month feeding study in male-Sprague-Dawley rats (10 g dextrin/kg bw/day), a higher testicle/body weight ratio than the controls was reported.[19] There was no increase in liver weight or ratio. The panel considered the testicular findings not toxicologically significant since there were no histopathological correlates. The study also reported that the animals gained more weight on the dextrin diet than on the standard rat chow but feed intake data were not reported.

Several short term studies aimed at determining the digestibility of dextrins compared to other carbohydrate diets were reported in the SCOGS panel report.[20] The digestibility of the

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16 FDA has recognized all of these ingredients derived from starch as GRAS. See 21 C.F.R. §184.1277 for Dextrin; see 21 C.F.R. §184.1444 for Maltodextrin; see 21 C.F.R. §184.1865 for Glucose Syrup; see 21 C.F.R. §184.1857 Glucose/Dextrose (corn sugar).

17 Select Committee on GRAS Substances (SCOGS) Report No. 75 (1975). Evaluation of the Health Aspects of Dextrin and Corn Dextrin as Food Ingredients. Contract No. FDA 223-75-2004, Life Sciences Research Office, Federation of American Societies for Experimental Biology.

18 Id.

19 Cohen, L., *et al.*, The Manifold Effects of Different Dietary Carbohydrates, Progr. Biochem. Pharmacol. 2: 182-202 (1967).

20 *See* Booher, L.E., *et al.*, Biologic Utilizations of Unmodified and Modified Food Starches, J. Nutr. 45: 75-95 (1951); Reussner, G., Jr., *et al.*, Studies on the Utilization of Various Starches and Sugars in the Rat, J. Nutr. 80: 291-298 (1963); Harper, A.E., *et al.*, Influence of

dextrin diets was usually lower than for starch, and no toxic effects were noted in the short term animal studies at doses up to 80 g/kg bw/day. Enlarged ceca were observed in most of the studies and attributed to the lack of digestibility of the dextrin.

The panel noted that "they found no reports on the allergenicity, carcinogenicity, teratogenicity, mutagenicity or fetotoxicity of dextrins." The panel concluded:

> "Animal feeding studies have shown dextrins to be digested and metabolized to a limited degree without toxic effects when fed at levels many times greater than those present from use of these products as direct food additives, . . . There is no evidence in the available information on dextrin and corn dextrin that demonstrates or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or that might be reasonably expected in the future." [Per capita consumption in 1972 was reported by the Panel to be 180 mg/p/day].

The SCOGS Panel Report did not indicate that the panel expected a toxicological problem with dextrins at higher doses, but simply responded to the existing conditions when anticipated uses were small.

2. Safety of Resistant Dextrin

As indicated above, Resistant Dextrin is a refined dextrin and, as such, it would be expected to be as safe or safer than the unrefined product. Nonetheless, to document the actual safety of the product offered in commerce, a series of toxicological studies were conducted on Resistant Dextrin. As discussed above (See Tables 1 and 3), NUTRIOSE® 6 and NUTRIOSE® 10 are both refined dextrins made from either corn or wheat. NUTRIOSE® 6 is prepared from the higher molecular weight fraction following removal of the lower molecular weight fraction through partitioning chromatography (See Fig 2.). As a result, NUTRIOSE® 6 has a slightly higher molecular weight than NUTRIOSE® 10 (Table 3) and higher fiber content. It, thus, has a slightly higher content of the "non-digestible" α- and β- linkages, and is a theoretical "worst-case" for toxicological testing, if such toxicity is the result of the non-digestible residues. The 90-day study and all the toxicological studies were conducted using NUTRIOSE® 6 as the "resistant dextrin."

Resistant Dextrin was administered to OFA-Sprague-Dawley rats (80 males and 80 females) in the diet in concentrations of 1.25%, 2.5% or 5% for 7 days a week for 90-consecutive days.[21] The published paper by Wils *et al*, describes the details of the protocol and the observations made. The study is a GLP study conducted consistent with OECD and RedBook

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Various Carbohydrates on the Utilization of Low Protein Rations By the White Rat, J. Nutr. 51: 523-537 (1953); Hundley, J.M., Influence of Fructose and Other Carbohydrates on the Niacin Requirement of the Rat, J. Biol. Chem. 181: 1-9 (1949).

[21] Wils, D., Scheuplein, R.J., Deremaux, L. and Looten, P.H., Safety profile of a food dextrin: acute Oral, 90-day rat feeding and mutagenicity studies. Food and Chemical Toxicol. 46: 3254-3261 (2008).

guidelines. There were no consistent, statistically-significant, dose-dependent adverse effects related to treatment including effects on mortality, behavior, body weight gain, absolute or relative organ weights or in food or water consumption. The only effect observed in the study was a 15% increase in the empty caecum weight for both male and female animals treated with 5% Resistant Dextrin. This was considered a physiological adaptation typically seen after consumption of high doses of nondigestible carbohydrates, not a toxicological effect. Resistant Dextrin is not completely digested and a large amount arrives in the caecum where it is partially fermented by intestinal bacteria. This generally leads to an increase in the caecum content and caecum mucosa. This same effect on the caecum occurs with polydextrose at comparable doses.[22]

The differences observed in blood chemistry in both male and female rats were slight and sporadic and were not considered toxicologically significant. Histological examination revealed no significant findings for female rats. The only significant histological finding in males was minimally increased periportal microvacuolation in hepatocytes and an increase in multifocal hemorrhagic suffusions in the thymus at the 5% level. Both these lesions are common for rats of this strain and age. Minimal increases in multifocal hemorrhagic suffusions in the thymus in the absence of other corroborative findings were not considered indicative of a treatment related effect. Neither of these lesions increased in females.

In summary, the study revealed no treatment-related toxic effects due to the feeding of Resistant Dextrin to rats at any dose. The concentrations tested are equivalent to doses of 1.12, 2.29, and 4.36 g/kg bw/day for males and 1.61, 3.08, and 6.50 g/kg bw/day for females. The highest no observed adverse effect level (NOAEL) from this study is 6.5 g/kg bw/day. The human equivalent consumption of approximately 6.5 g/kg bw/day (assume a 60 kg person) would be 390 g/person/day. An ADI can be derived from NOAEL/appropriate safety factor or 6.5 g/kg bw/day/100 x 60 kg or 3.9 g/person/day.

The potential mutagenic activity of Resistant Dextrin was studied in the Ames test, and in L5178Y mouse lymphoma cells using a mutation assay at the TK locus. Resistant Dextrin did not induce mutagenicity in the Ames test nor in the mouse lymphoma mutation assay.

3. Allergenicity

Resistant Dextrin is made from dextrin derived from corn or wheat starch. Wheat gluten and other wheat proteins have not been detected in Roquette's Resistant Dextrin derived from wheat. Wheat gluten is not detected (<3.1 ppm) with R5 Sandwich Elisa Kit and not detected (<2 ppm) with Morinaga Elisa kit. Nevertheless, Roquette identifies this Resistant Dextrin as derived from wheat and advises its customers to label the ingredient as derived from wheat, *e.g.*, "wheat resistant dextrin" or "resistant wheat dextrin."

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[22] Burdock, G.A. and Flamm, W.G., A Review of the Studies of the Safety of Polydextrose in Food, Food and Chemical Toxicology. 37: 233-264 (1999).

4. Safety of Polydextrose

Polydextrose is recognized as an approved food additive for use at levels consistent with current good manufacturing practice (cGMP) as a bulking agent, formulation aid, humectant, and texturizer in all food (except meat and poultry and infant formula).[23] Polydextrose and Resistant Dextrin are both mixed polymers of glucose, have a similar molecular weight distribution and similar glycosidal bonding. The similarity in the two substances is shown in Table 1. The fundamental difference is in the way they are produced. Polydextrose is polymerized from glucose whereas Resistant Dextrin is hydrolyzed from starch.

The FCC defines polydextrose as: "a randomly bonded polymer prepared by the condensation of a melt that consists of approximately 90% D-glucose, 10% sorbitol, and 1% citric acid or 1% phosphoric acid on a weight basis. The 1,6-glycosidic linkage predominates in the polymer, but other possible bonds are present. The product contains small quantities of free glucose, sorbitol, and D-anhydroglucoses (levoglucosan), with traces of citric acid or phosphoric acid."[24]

Since Resistant Dextrin and polydextrose appear to be chemically similar or equivalent, their toxicological profiles should also be similar. There is very little difference in the amount of digestible versus non-digestible bonding, so both substances are expected to resist mammalian digestion to approximately the same extent, produce ceacal enlargement if doses are high enough, and be essentially non-toxic at high doses. These conclusions are supported by the studies on polydextrose and Resistant Dextrin.

A JECFA toxicological monograph was prepared for polydextrose in 1981.[25] The studies in this monograph provided a basis for an initial JECFA ADI of 70 mg/kg bw. The ADI was primarily based on studies in dogs, which are more sensitive to the laxation and diarrheal effects of large amounts of fermentable carbohydrate.

Polydextrose was re-evaluated by the 31st meeting of JECFA (1987) and allocated an "ADI not specified." Polydextrose showed no toxic effects in acute, subacute, and chronic studies in three animal species at a level equivalent to 10% in the diet.

A major review of the toxicological data on polydextrose was published by Burdock and Flamm.[26] This data included a 2-year carcinogenicity study in rats, an 18 month chronic study in

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[23] 21 C.F.R. §172.841.

[24] See Food Chemicals Codex 7th Edition (2010), Polydextrose, p.811.

[25] International Programme of Chemical Safety (IPCS), WHO Food Additive Series 16, Polydextroses No. 512 (March 23, 1981), *available at*, http://www.inchem.org/documents/jecfa/jecmono/v16je18.htm.

[26] Burdock, G.A. and Flamm, W.G., A Review of the Studies of the Safety of Polydextrose in Food, Food and Chemical Toxicology. 37: 233-264 (1999).

mice, a three generation reproduction study in rats, 3, 6, 13 and 24 month studies in dogs, and several other short-term studies.

There are two forms of polydextrose: polydextrose A and N. Polydextrose-A (PD-A, the acid form) is an amorphous, slightly acid, fusible powder. Polydextrose-N (PD-N, the neutralized form) is available as a 70% aqueous solution, obtained by addition of KOH or K_2CO_3 to a solution of PD-A. Toxicity studies were conducted on both these compounds and there was little difference found in the toxicity between them. The dog is the most sensitive species to the diarrheal effects because as a carnivore it is unable to tolerate large amounts of fermentable carbohydrate. PD-N, with high level of potassium, enhances this effect. Both forms have an extremely low acute toxicity. The only adverse finding in rats was diarrhea following the administration of very high doses (> 60 g/kg.bw/day). Soft stools and not diarrhea were observed at doses of approximately 10 g/kg.bw/day (10% in the diet). Burdock and Flamm concluded, " . . . rats may repeatedly consumed up to 10 g/kg body weight / day PD without untoward effects."

Burdock and Flamm reported that the sensitivity to the osmotic effects of polydextrose varied with species; the dog was the most sensitive species for diarrheal effects. At doses of 8 g/kg.bw/day or above, dogs responded with diarrhea, low urinary sodium and hypocalcaemia. The authors note that this pathology was observed, "in the 13 month dog study at the high dose, 8 g/kg body weight/day, with a possible no-adverse effect level at the low dose of 4 g/kg body weight/day." Application of the 100-fold safety factor to the dog or rat study would result in ADI's of 40 mg/kg/day or 100 mg/kg, respectively or 2.4 g/day or 6 g/day, respectively, for a 60-70 kg body weight individual. Burdock and Flamm note that clinical studies show that the only laxative effects (not diarrhea) are observed in humans up to 90g/p/day. This indicates that a 100-fold safety factor is not appropriate.

5. Laxation Potential of Resistant Dextrin

The digestive effects produced by foodstuffs including polyols, dietary fiber, and certain fruits and vegetables are dependent upon the quantity consumed and the nature of the foodstuff. The excessive consumption of certain poorly digested foods can produce gastro-intestinal effects that result in the retention of water in the gastrointestinal tract. In reference to the nature of the low digestible foodstuff, the digestive effects may be influenced by the molecular weight, molecular structure, and the affinity of the microflora to the specific foodstuff. Since Resistant Dextrin acts as a dietary fiber, Roquette has examined both the short-term and long-term tolerance of Resistant Dextrin.

Resistant Dextrin, a dietary fiber only partially digested in the small intestine, is fermented relatively slowly in the colon, which can result in flatus, borborygmi, and abdominal discomfort in certain individuals if the doses exceed 45 g/person/day.[27] The fermentation typically results in positive digestive effects including, but not limited to, a lowering of the

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[27] Pasman, W., Wils, D., Saniez, M-H., and Kardinaal, A., Long-term gastrointestinal tolerance of NUTRIOSE® FB in healthy men. Eur. J. Clin. Nutr. 60: 1024-1034 (2006).

colonic pH, an increase in short chain fatty acid production, an increase in α-glucosidase and β-glucosidase concentration, and a decrease in the gastro-intestinal transit time. As a result of the slow fermentation combined with the positive digestive effects, Resistant Dextrin may produce beneficial health effects.[28]

a. Tolerance Studies on Resistant Dextrin

In two published human studies sponsored by Roquette, no diarrhea or other treatment-related effects in adults at doses of Resistant Dextrin up to 30 g/p/d were reported.[29] The only effects considered related to treatment were sporadic flatus and borborygma. Assuming children are equally as sensitive on a body weight basis, which appears to be the case, a conservative diarrhea threshold for children may be obtained by dividing the maximum non-laxative dose for a 60 kg adult (45g/p/d) by 3, correcting for the approximate 20/60 weight ratio between children and adults, resulting in a non-laxation dose for children of approximately 15 g/p/d. A third study was designed primarily to determine the energy value of Resistant Dextrin and its effect on mineral absorption, but also included an assessment of gastrointestinal tolerance.

i) Short Term (21 days) Tolerance in Humans

The study was designed to measure short term gastrointestinal discomfort, including number and texture of stools, flatulence, borborygma, bloating, and stomach cramps. Twenty healthy males (divided randomly into two groups of 10) age 20-44 yrs, BMI 20.1-29.5 kg/m^2, were administered doses of Resistant Dextrin in food in a randomized, placebo-controlled, multiple dose, double-blind crossover study.[30] All subjects received a placebo, Glucidex®, a maltodextrin, in a seven day run-in period. Ten subjects received 10, 30, and 60 g/day of Resistant Dextrin or placebo; the other ten subjects received 15, 45, and 80 g/day of Resistant Dextrin or placebo. Each dose was administered for seven days and consumed in four divided doses, breakfast, morning, lunch, and dinner. After 21 days, the groups received a placebo washout for seven days and then crossed over to either placebo or treatment. During the study the subjects were asked to limit their fiber intake and to exclude food containing pre- and pro-biotics. On the first and on each 7th day of the study the subjects were monitored for

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[28] Van den Heuval, E.G.H.M., Wils, D., Pasman, M., Saniez, M-H and Kardinaal, A.F.M., Dietary supplementation of different doses of NUTRIOSE®FB, a fermentable dextrin, alters the activity of faecal enzymes in healthy men. Eur. J. Clin. Nutr. 44: 445-451 (2005).

[29] The two studies are cited in footnote 28 and 29 below. We have focused on a review of the information as it pertains to consumption of Resistant Dextrin at up to 30 g/day. The original TNO long-term study Report cites one possible incidence of diarrhea at 45 g/day but this was not discussed in the TNO Report nor mentioned in the related published paper because it was not considered significant by the authors.

[30] Van den Heuval, E.G.H.M., Wils, D., Pasman, W.J., Bakker, M., Saniez, M-H and Kardinaal, A.F.M., Short-term digestive tolerance of different doses of NUTRIOSE®FB, a food dextrin, in adult men. Eur. J. Clin. Nutr. 58: 1046-1055 (2004).

gastrointestinal complaints, compliance, food habits, and satiety. Breath hydrogen, body weight changes, and any dietary changes were measured less frequently.

Resistant Dextrin was well tolerated up to a dose of 45 g/day. Higher doses (> 45 g/day) resulted in an increase in flatulence relative to the control diets having the same levels of Glucidex 6, but no diarrhea was observed at any dose. The residuals of Resistant Dextrin, reflected by the amount of polymerized glucose recovered in the feces, increased with the dose of Resistant Dextrin. Enzymatic activity (α- and β- glucosidase) increased with each dose beyond 15 g/d. Flatulence might lessen with longer exposure due to adaptation by colonic flora.

ii) Longer Term (4-5 weeks) Tolerance in Humans

Based on results from the short term study, Resistant Dextrin was tested for gastrointestinal tolerance over a longer period, in a randomized, placebo-controlled, parallel, double-blind study.[31] Forty-eight healthy adult subjects (male, age 34.7 $\pm$ 8.2 years; BMI 24.9 $\pm$ 3.3 kg m^2), 16 subjects/group received either placebo (Glucidex), 30 g Resistant Dextrin, or 45 g Resistant Dextrin daily for 4-5 weeks. Forty-three subjects completed the study. Subjective evaluation of well being and GI comfort were examined by a questionnaire on complaints, occurrence, and severity of abdominal symptoms.

Daily ingestion of 30 g or 45 g was well tolerated except for a tendency for increased flatulence, but the increase was not substantial compared to those receiving the control (13 control subjects reported flatulence during the last six days versus 14 persons receiving 30 g and 17 persons receiving 45 g). The product was well fermented, which resulted in an increase in *Lactobacilli* and the enzyme content of α-glucosidase and β-glucosidase, indicating that Resistant Dextrin has pre-biotic characteristics.

Other studies designed primarily to determine the energy value of Resistant Dextrin and its impact on mineral absorption and retention, discussed in greater detail below, demonstrated that the ingestion of Resistant Dextrin did not cause digestive disorders, except excessive flatulence and slight abdominal pain in some subjects for intakes above 50 g/d.[32] The authors concluded that Resistant Dextrin could be safely substituted for usual maltodextrins up to 50g/d. The study was composed of two successive parts, a preliminary study and a main study. The preliminary study was aimed at determining the tolerance to Resistant Dextrin and training subjects to the experimental design. In the preliminary study, ten healthy men, non smokers, 23.6 (SD 2.6) years, BMI 22.3 (SD 1.6) kg/m^2 received divided doses of Resistant Dextrin from 20 g to 100 g over a 20 day period. In the main study, the same ten subjects received one of two

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31 Pasman, W., Wils, D., Saniez, M-H, and Kardinaal, Long-term gastrointestinal tolerance of NUTRIOSE®FB in healthy men. Eur. J.Clin. Nutr. 60: 1024-1034 (2006).

32 Vermorel, M., Coudray, C., Wils, D., Sinaud, S., Tressol, J.C., Montaurier, C., Vernet, J., Brandolini, M., Bouteloup-Demange, C. and Rayssiguier, Y., Energy value of a low-digestible carbohydrate, NUTRIOSE®FB, and its impact on magnesium, calcium and zinc apparent absorption and retention in healthy young men. Eur. J. Nutr. 43: 344-352 (2004).

diets (dextrose or Resistant Dextrin) according to a cross-over design, with a wash-out period of 4 weeks between the two treatment periods. Each experimental period lasted for 31 days, and included progressive adaptation from 20 g to 100 g/day over 18 days, followed by 13 days with a constant intake of 100 g/day of the tested products. Subjects were asked to complete a diary indicating the occurrence and intensity of gas emission, borborygma, flatulence, abdominal pain, and diarrhea. Two subjects mentioned mild diarrhea occurring just once during the preliminary study, but not in the main study, suggesting that adaptation was occurring. The main symptom reported was flatulence. The intensity of gastrointestinal effects decreased over the 20 day period.

6. Impact on Mineral Absorption and Retention

In studies designed to determine the energy value of Resistant Dextrin and its impact on mineral absorption and retention, ten healthy young men (mean age 26.3 years old) received Resistant Dextrin in six equal doses daily.[33] In a preliminary study, subjects received increasing doses of Resistant Dextrin from 20 g to 100 g over a 20 day period. In the main study, subjects received one of two diets (dextrose or Resistant Dextrin) according to a cross-over design, with a wash out period of 4 weeks between the two treatment periods. Each experimental period lasted for 31 days, and included progressive adaptation from 20 g to 100 g/day over 18 days, followed by 13 days with a constant intake of 100 g/day of the tested products.

The authors reported that the ingestion of Resistant Dextrin "significantly increased the relative apparent absorption of Mg and Mg retention by 67% and 31 mg/d, respectively, tended to increase Ca apparent absorption (P=0.110) and retention (p=0.059), but did not significantly alter Zn parameters." This improvement in apparent magnesium absorption was accompanied by significant increases in magnesium urinary excretion and magnesium retention. These studies confirm what had been observed in laboratory animals, that Resistant Dextrin does not adversely affection mineral metabolism in the body. The authors concluded that Resistant Dextrin can be used as a "bulking agent' and substituted up to 50 g/d for usual maltodextrins without causing digestive disorders in healthy subjects.

G. Conclusions

Based on the documentation provided in this GRAS Notification, and as discussed above, Keller and Heckman LLP, on behalf of our client Roquette, has concluded that Resistant Dextrin is GRAS via scientific procedures for use as a bulking agent and as a dietary fiber ingredient in foods (excluding meat products, poultry products, and infant formula). In addition, the Expert Panel who has critically evaluated this GRAS Notification and other relevant documentation has

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[33] Vermorel, M., Coudray, C., Wils, D., Sinaud, S., Tressol, J.C., Montaurier, C., Vernet, J., Brandolini, M., Bouteloup-Demange, C. and Rayssiguier, Y., Energy value of a low-digestible carbohydrate, NUTRIOSE®FB, and its impact on magnesium, calcium and zinc apparent absorption and retention in healthy young men. Eur J. Nutr. 43: 344-352 (2004).

concluded that the proposed uses of Resistant Dextrin are GRAS, based on scientific procedures[34]

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[34] The Expert Panel GRAS Conclusion is available at **Appendix II.**

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EXPERT PANEL OPINION

The Generally Recognized as Safe (GRAS) Status of Roquette's Resistant Dextrin for Use in Food as a Bulking Agent and as a Dietary Fiber Ingredient

05 June 2012

An independent panel of experts, qualified by their scientific training and national and international experience to evaluate the safety of food and food ingredients (the "Expert Panel"), was specially convened by Keller and Heckman LLP, on behalf of their client Roquette Frere (Roquette), to evaluate the safety and "Generally Recognized As Safe" ("GRAS") status of the proposed uses of Resistant Dextrin derived from corn or wheat in multiple food applications. The safety evaluation focused on two Resistant Dextrin products, Nutriose® 6 and Nutriose® 10, which are Roquette's trade names for Resistant Dextrins. Nutriose® 10 contains higher levels of mono- and disaccharides than Nutriose® 6, but the composition of the higher molecular weight oligomers is the same in both versions. As a result, there is a slight difference in the average molecular weight and degree of polymerization that produces slightly different physical properties of commercial value.

Resistant Dextrins are intended for use in food as bulking agents and as dietary fiber ingredients in multiple food categories at approximately three to nine grams per serving, including baked goods, beverages liquid non-dairy, cereals and granola bars, condiments and dressings, confections, dairy beverages, dairy non-beverages, frozen desserts, gravies and sauces, meal replacements, pasta and grain products, prepared meals and soups, processed fruits, shelf-stable desserts, snacks and crackers, and dry beverage powder.

The Expert Panel reviewed a dossier, "GRAS Notification for Resistant Dextrins" (2012), prepared by Keller and Heckman LLP, that summarized the manufacturing processes for Resistant Dextrins including the safety of the substances used in manufacturing, the results of analyses of the finished products for toxigenic substances and microbial pathogens of potential concern, specifications for the Resistant Dextrin products, and safety information. The Expert Panel also reviewed other materials deemed appropriate.

Dextrins (the starting material for Resistant Dextrins), polydextrose (a glucose polymer with similar atypic bondings as those found in Roquette's Resistant Dextrins), and Resistant Dextrins are starch-based food ingredients. The metabolic fate of these three food ingredients is essentially the same; that is, they are degraded in the gastro-intestinal tract to the same components including starch, dextrins, maltodextrins, and glucose. It may be concluded that these three food ingredients are substantially chemically equivalent and toxicologically equivalent. Therefore, it is appropriate to consider the extensive published safety data on dextrins and polydextrose in evaluating the safety of Resistant Dextrins. In addition, the published safety data on Roquette's Resistant Dextrin were considered.

The estimated daily intakes (EDIs) for Roquette's Resistant Dextrins are 17.1 g/day and 32.5 g/day at the mean and 90th percentile, respectively. JECFA allocated an "ADI not specified" for polydextrose.

The NOAEL of Resistant Dextrin in OA Sprague –Dawley rats was 5% in the diet, equivalent to 4.36 g/kg bw/day for males and 6.50 g/kg bw/day for females. Resistant Dextrin was not mutagenic in the Ames test and in the L5178Y mouse lymphoma assay. The NOAEL for polydextrose was 10 g/kg bw/day for rats and 4 g/kg bw/day for dogs. A single dose feeding study of 10 g/kg bw/day of dextrin to male Sprague-Dawley rats for 18 months failed to elicit significant toxicity. Acute, short-term and long-term studies demonstrate very low toxicity for these three food ingredients. SCOGS (1975) did not report any concerns about the GRAS status of dextrins.

Conclusion

Following its independent and critical evaluation of the material summarized in the dossier, "GRAS Notification for Resistant Dextrin," and other materials deemed appropriate, the Expert Panel convened by telephone, and independently, jointly, and unanimously concluded that the intended uses as bulking agents and as dietary fiber food ingredients in multiple food applications, including baked goods, beverages liquid non-dairy, cereals and granola bars, condiments and dressings, confections, dairy beverages, dairy non-beverages, frozen desserts, gravies and sauces, meal replacements, pasta and grain products, prepared meals and soups, processed fruits, shelf-stable desserts, snacks and crackers, and dry beverage powder.of Roquette's Resistant Dextrins, manufactured consistent with current good manufacturing practice (cGMP) and meeting appropriate food-grade specifications presented in the GRASN, are safe and suitable.

The Expert Panel also unanimously concluded that the proposed uses of Roquette's Resistant Dextrins, manufactured consistent with current good manufacturing practice (cGMP) and meeting appropriate food-grade specifications presented in the GRASN, are Generally Regarded As Safe (GRAS) based on scientific procedures supported by a long history of safe use of starch and starch-based food ingredients.

It is the opinion of this Expert Panel that other qualified experts would concur with these conclusions.

(b) (6)

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Exponent®

Center for Chemical Regulation and Food Safety

Estimated Daily Intake of Resistant Dextrin from Selected Foods in the US

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Estimated Daily Intake of Resistant Dextrin from Selected Foods in the US

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List of Acronyms

CFR	Code of Federal Regulations
EDI	Estimated Daily Intake
NHANES	National Health and Nutrition Examination Survey
NCHS	National Center for Health Statistics
RACC	Reference Amounts Customarily Consumed
USDA	United States Department of Agriculture

INTRODUCTION

At the request of Keller and Heckman, Exponent has calculated the estimated daily intake (EDI) of resistant dextrin from selected "better for you" or "healthier for you" foods from 16 broad food categories. Resistant dextrin is proposed for use in selected foods from the following broad categories: dairy and non-dairy beverages, dairy products, frozen desserts, meal replacements, dry beverage powders, shelf stable desserts, gravies and sauces, prepared meals and soups, baked goods, cereals[1] and granola bars, snacks and crackers, pasta and grain products, processed fruits, condiments and dressings, and confections. The resistant dextrin inclusion rate ranges from 3 to 9 grams per serving of food.

[1] All hot and cold breakfast cereals reported consumed in the NHANES 2003-2006 were assumed to contain resistant dextrin.

DATA AND METHODS

The EDI of resistant dextrin based on the proposed uses in 16 food categories was calculated using food consumption data collected in the National Health and Nutrition Examination Surveys (NHANES) conducted in 2003-2004 and 2005-2006 (NCHS 2007, 2008). The combined NHANES 2003-2004 and NHANES 2005-2006 is a complex multistage probability sample designed to be representative of the civilian U.S. population. Two days of food intake data, in addition to nutrition, demographic, and health information, were collected in each survey. The NHANES survey over-samples minorities, low-income groups, adolescents ages 12-19 years, and adults 60 years of age and older. Statistical weights are provided by the National Center for Health Statistics (NCHS) for the surveys to adjust for the differential probabilities of selection. A total of 16,783 individuals in the survey period 2003-2006 provided 2 complete days of dietary recalls.

The 16 food categories include selected "better for you" or "healthier for you" foods from the following categories: dairy and non-dairy beverages, dairy products, frozen desserts, meal replacements, dry beverage powders, shelf stable desserts, gravies and sauces, prepared meals and soups, baked goods, cereals[2] and granola bars, snacks and crackers, pasta and grain products, processed fruits, condiments and dressings and confections. The "better for you" and "healthier for you" foods were selected from foods reported consumed in NHANES 2003-2006 survey period by identifying foods with descriptions that included low or reduced in sugar, sodium, fat or calories, or high in fiber or listed as whole wheat. More specific inclusion criteria for each broad food category can be found in Appendix 1.

[2] All hot and cold breakfast cereals reported consumed in the NHANES 2003-2006 were assumed to contain resistant dextrin.

In some cases resistant dextrin was applied to only a portion of the food reported consumed. For the gravies and sauces category, resistant dextrin was applied to the sauce portion only of a mixed dish (e.g., spaghetti with tomato sauce). There were so few sauces that were listed as low in calorie or low fat, that a conservative approach was taken to include resistant dextrin in all tomato based sauces in mixed dishes. In the case that resistant dextrin is proposed for only a portion of a mixed dish, the recipe for each food was used to determine the percent of the dish that is sauce and resistant dextrin was applied to only this percent of the food reported consumed. In these cases of mixed dishes, the serving size of portion of interest (e.g., spaghetti sauce, 125 g) was used rather than the serving size for the entire mixed dish (approximately 240 g). This affected the gravies and sauces, snacks and crackers and baked goods included in mixed dishes. Appendix 2 lists all foods reported consumed in NHANES 2003-2006 that were included in the analysis and any food that only a portion was included in the analysis is noted with an asterisks.

In addition, all hot and cold cereals reported consumed in the NHANES 2003-2006 were assumed to contain resistant dextrin. The inclusion criteria were sufficiently broad that a worst case estimate (i.e., all breakfast cereals) was assumed.

Exponent estimated the daily intake on a "per user" basis. In this analysis, a "user" is anyone who reported consuming a food on either of the survey days. This approach is consistent with the definition of "user" followed by the United States Department of Agriculture (USDA). We identified each individual who reported consuming a food on either of the survey days, and we used that individual's responses for both survey days. Zero consumption days were included in calculating that individual's average daily intake. Provided the ingredient/contaminant of interest is not an acute toxicant or teratogen, it is appropriate to average exposures over a longer period than one day. Therefore, Exponent used each respondent's food consumption averaged over the two days of the NHANES 2003-2006 survey. For example, if a person reported consuming 240 grams of a beverage on day 1 and 120 grams of a beverage on day 2,

his/her 2-day average beverage consumption would be 180 grams ([240+120]/2). A 2-day average typically overestimates long-term (chronic) daily intake; however, food consumption data are available for only two nonconsecutive days in the most recent NHANES 2003-2006 survey database. Exponent believes, however, that these are the best publicly available dietary intake data for the US at this time for this analysis.

Exponent used the statistically weighted values from the survey in its analyses. The statistical weights compensate for variable probabilities of selection, adjust for non-response, and provide intake estimates that are representative of the U.S. population and the selected age-gender subgroups.

The resistant dextrin use rate for the proposed foods ranges from 3 g/serving to 9 g/serving. The serving size for each proposed NHANES 2003-2006 food code for the 16 broad food categories was derived from the Chapter 21 of the Code of Federal Regulations, Section 101.12 Reference Amounts Customarily Consumed (RACC) and can be found in Appendix 2.

RESULTS

EDI from Proposed Uses of Resistant Dextrin

The resistant dextrin use rate for selected foods ranges from 3 g/serving to 9 g/serving. Using these maximum use rates, Exponent calculated the EDI of resistant dextrin from selected better for you/healthier for you foods with the latest publicly available food consumption data (NHANES 2003-06).

Estimated daily intake of resistant dextrin from selected broad food categories for the overall US population is 32.6 g/day (0.6 g/kg bw/day) at the *per user* 90^{th} percentile. The *per user* 90^{th} percentile for the various age and gender subgroups ranged from 20.2 g/day (children 1 to 6 years) to 39.3 g/ day (males 20+ years). Nearly all people in the total US population and each of the selected subpopulations reported eating at least one food containing resistant dextrin (% users are all $\geq$ 98%). See Table 1.

Table 1. *Per User* Estimated Daily Intakes of Resistant Dextrin from Selected Uses

Populations	g/day	g/kg-bw/day	% Users
Total US			98.6%
Mean	17.4	0.3	
90th percentile	32.6	0.6	
Children 1-6 y			99.8%
Mean	11.6	0.7	
90th percentile	20.2	1.2	
Children 7-12 y			99.8%
Mean	14.5	0.4	
90th percentile	25.6	0.7	
Males 13-19 y			99.2%
Mean	17.4	0.3	
90th percentile	31.4	0.5	
Females 13-19 y			99.2%
Mean	13.6	0.2	
90th percentile	27.0	0.5	
Males 20+ y			99.1%
Mean	21.0	0.2	
90th percentile	39.3	0.5	
Females 20+ y			99.5%
Mean	16.6	0.2	
90th percentile	30.4	0.4	

EDI from Broad Food Categories

The EDI of resistant dextrin was also calculated by broad food category in order to view the contribution of each food group to the overall total intake. Non-dairy liquid beverages, cereals and granola bars, baked goods, condiments and dressings, and snacks and crackers were the greatest contributors to overall resistant dextrin intake on a *per capita* basis by the US population. These five food groups contributed to 80% of the total US population mean intake of resistant dextrin and more than half of the US population reported eating at least one food from each of four of the food categories (only 36% of the population reported eating a resistant dextrin containing snack or cracker). Please note that results at the 90th percentile as well as *per user* results cannot be summed to equal the total US population EDI because the user populations for each broad food category are different. See Table 2.

Table 2. US *Per Capita* and *Per User* Estimated Daily Intake for Resistant Dextrin from Broad Food Categories (g/person/day)

Food Group	Unweighted Total People	Unweighted Total Users	Percent Users	Per Capita (g/day)		Per User (g/day)	
				Mean	90th Percentile	Mean	90th Percentile
Baked Goods	16783	10338	64%	1.8	4.6	2.8	5.4
Beverages liquid-non dairy	16783	11426	71%	6.9	18.0	9.7	21.7
Cereals and Granola Bars	16783	8752	51%	3.1	8.9	6.0	11.4
Condiments and Dressings	16783	8118	50%	1.4	4.2	2.8	6.3
Confections	16783	205	1.2%	0.01	0	1.0	2.9
Dairy Beverage	16783	1873	15%	0.5	1.5	3.2	6.9
Dairy Non-Beverages	16783	4042	27%	0.5	1.7	1.9	3.8
Frozen Desserts	16783	1117	8%	0.2	0	1.9	3.7
Gravies and Sauces	16783	6489	38%	0.6	2.1	1.7	3.5
Meal Replacements	16783	143	1.3%	0.04	0	3.2	6.4[1]
Pasta and Grain Products	16783	1042	5.5%	0.1	0	1.7	3.1
Prepared meals and soups	16783	2165	12%	0.3	0.8	2.2	4.1
Processed Fruit	16783	2010	12%	0.3	0.5	2.3	4.9
Shelf stable desserts	16783	451	2.6%	0.05	0	1.9	3.0
Snacks and Crackers	16783	5641	36%	1.0	3.1	2.7	6.2
Dry Beverage Powder	16783	1903	12%	0.5	1.5	3.9	7.9
All Foods Combined	**16783**	**16223**	**99%**	**17.1**	**32.5**	**17.4**	**32.6**

[1] Estimates at the 90th percentile are statistically unreliable due to insufficient sample size.

DISCUSSION

The EDI of resistant dextrin for the 90th percentile consumers in US population is 32.6 g/day (0.6 g/kg-bw/day). Nearly every person in the US reported consuming a food proposed to contain resistant dextrin (98.6% users). Males ages 20+ years who reported eating at least one food containing resistant dextrin (*per user*) have the greatest 90th percentile intake of 39.3 g/day. Non-dairy beverages, cereals and granola bars, baked goods, condiments and dressings and snacks and crackers were the greatest contributors to the overall resistant dextrin intake in the US population on a *per capita* basis. These five categories accounted for 80% of the total *per capita* US population mean intake.

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US Code of Federal Regulations Title 21 Food and Drugs Part 101 Food Labeling, Section 12, Reference Amounts Customarily Consumed (21CFR101.12)

APPENDIX 1. Inclusion Criteria

Categories	Amount per RACC[3] serving	Benefit/functionality (in addition to source of fiber)	Examples of food items	Additional Comments
Dairy Beverage	3 grams			
		Skim milk or non-fat milk as key milk applications Provides a good mouth feel to mimic the 2% milk Half-n-half cream that is better for you in fat and calorie reduction with good mouth feel Fruit smoothie made with fruit juice and/or dairy products that provide a good mouth feel	Milk, half-n-half, fruit smoothie	Included chocolate beverages that were made with skim or 1% milk. Excluded carry out milk shakes (McDonalds, Burger King etc)
Dairy - non beverage	3 grams			
		Fruit flavored, low or no sugar, low or no fat, may include artificial sweetener. Source of fiber in "healthy image" yogurts and may help in maintaining proper functioning of the digestive system Reduced fat cheese-like products to aid in maintaining the flavor and texture when reducing the fat content	Yogurt (not frozen) Cheese spreads	
Frozen desserts	3 grams			
		Primary market segment is no sugar added (NSA) and reduced fat	Frozen yogurt, frozen dairy desserts, ice	

[3] Reference Amounts Customarily Consumed: 21 CFR 101.12

Categories	Amount per RACC[3] serving	Benefit/functionality (in addition to source of fiber)	Examples of food items	Additional Comments
		"healthier image" NSA and reduced fat frozen desserts (i.e. fruit flavored, low or no fat) Provides a good mouth feel	cream, fruit bars Excluded chocolate flavor	
Meal Replacement	3 grams			
		Primary markets are for reduction in sugar and reduction in calories as part of overall weight management program. A "better for you" breakfast/meal replacement. In addition, provide a good mouth feel to the beverage.	Instant breakfast; meal replacement; plant protein products/meat substitutes; ready to drink or dry powder	
Dry Beverage Powder				
	3 grams	Dry powder mix with water or milk for a beverage, not a meal replacement, application. Primary markets include a reduction in sugar/fat/calories as part of an overall weight management program. In addition, provide a good mouth feel to the beverage.	cocoa, instant flavored coffee or tea	
	9 grams	Primary market is "healthier image" beverages. Functions as a carrier in dry powder mixes with additional fiber. In addition provides good mouth feel.	dry powder mixes for addition to water (i.e. nutritional, sports drinks, flavored stick packs)	
Shelf stable desserts				
	3 grams	Primary markets are for reduction in sugar, fat, and calories. A "better for you" snack. Provides good mouth feel for	pudding, gelatin	Included chocolate flavor pudding Exclude baby foods

Categories	Amount per RACC[3] serving	Benefit/functionality (in addition to source of fiber)	Examples of food items	Additional Comments
		reduced fat varieties.		
Gravies and Sauces				
	3 grams	Primary markets are for reduction in sugar, fat, and calories. A "better for you" sauce/gravy. Provides good mouth feel for reduced fat varieties.	gravy, pizza sauce, tomato spaghetti sauce	The portion of gravies and sauces needs to be extracted from mixed dishes.
Prepared meals and Soups				
	3 grams	"Better for you" prepared meals and soups including reduction in sugar, fat, and calories. Reduced sodium products would also be of interest. In addition, acts as a binder and improves mouth feel in "better for you" formulated products, including meat analogs (i.e. "veggie burgers", "meatless meatballs").	frozen or shelf packaged prepared meals, meat analogs, "healthier image" soups, breading	Included "healthier" frozen meals (e.g. Healthy choice, lean cuisine and other diet froze meals.) Included, "healthy request soups"
Baked goods				
	3 grams	"Better for you" baked goods and "healthy image" breads such as wheat and whole grain. For cookies, brownies, cakes, and sweet rolls includes reduction in sugar, fat, and calories Acts as a bulking agent in reduced sugar and reduced fat dry mixes	bread, cakes, brownies, cookies, muffins, bread rolls, sweet rolls, doughnuts, bagels, English muffins, biscuits, pie, pancakes, waffles, tortillas For muffins, pancakes, waffles,	Does not include fresh bread from the bakery.

Categories	Amount per RACC[3] serving	Benefit/functionality (in addition to source of fiber)	Examples of food items	Additional Comments
			biscuits: the primary market is mixes and the secondary market is prepared	
Cereals and Granola bars				
	6 grams	"Better for you" and "healthy image/nutrition" bars. Includes reduction in fat and calories. Acts as a binder in the bars. "Better for you" and "healthy image/nutrition" cereal. Includes reduction in sugar and calories. Acts as a binder in the cereal. "Healthy image" hot cereals.	Chewy and hard granola bars, Kellogg's breakfast bars, Nutrigrain cereal bars Kellogg's and General mills cold cereals Quaker oat cereals and cream of wheat cereals	Included all breakfast cereals, regardless of brand.
Snacks/Crackers				
	3 grams	"Better for you" snacks including fat, calorie, and sodium reduction. Acts as a binder and stabilizer in extruded foods.	Saltines, graham, wheat, potato chips, pretzels; nondairy dips	
Pasta and grain products				
	3 grams	"Better for you" pasta including fat and calorie reduction and whole grain or wheat pastas. Acts as a binder and stabilizer in extruded foods "Better for you" instant rice dishes including reduction in fat and sodium and brown rice.	Dry pasta sold for cooking at home (i.e. spaghetti, macaroni) Uncle Ben's instant/quick rice dishes	Included pasta portions of mixed dishes. Dishes such as hamburger helper, Mac n' Cheeze were excluded (not "healthier or better for you" options)

Categories	Amount per RACC[3] serving	Benefit/functionality (in addition to source of fiber)	Examples of food items	Additional Comments
Processed fruits				
	3 grams	Sugar reduction in processed fruits. Provides good mouth feel in the fruits.	Dried fruit, applesauce	Included only the fruit originally highlighted by client (peaches, pears, pineapple, cranberry)
Condiments/Dressings				
	3 grams	"Better for you" marinating sauces "Better for you" salad dressings including reduction in fat and calories. Provides good mouth feel to mimic the full fat dressings.	Barbeque sauce, soy sauce, marinades Ranch, thousand island, mayonnaise like product, pancake syrup	BBQ sauces were included despite not having a "better for you" status.
Confection				
	3 grams	"Better for you" sweet treats including reduction in sugar, calories, fat. Provides good mouth feel and helps controls crystallization.	hard candy, soft candy, chocolate, caramel, chewing gum, mints, icings for baked goods,	
Beverage - liquid (non-dairy)				
	3 grams	"Better for you" beverages and "healthy image" beverages with reduction in sugar and calories. Provides good mouth feel and solubility.	Bottled vitamin water, fruit juices, sports drinks, energy drinks, carbonated and non-	

Categories	Amount per RACC[3] serving	Benefit/functionality (in addition to source of fiber)	Examples of food items	Additional Comments
			carbonated nutritional beverage (i.e. added vitamins, antioxidants, protein, etc.),	

APPENDIX 2. NHANES Food Codes Included in Proposed Use of Resistant Dextrin in Select Foods

Baked Goods

Food Code	Baked Goods: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
51000100	Bread, NS as to major flour	3	50
51000110	Bread, NS as to major flour, toasted	3	50
51000180	Bread, made from home recipe or purchased at a bakery, NS as to major flour	3	50
51000200	Roll, NS as to major flour	3	50
51000300	Roll, hard, NS as to major flour	3	50
51101000	Bread, white	3	50
51101010	Bread, white, toasted	3	50
51122000	Bread, reduced calorie and/or high fiber, white or NFS	3	50
51122010	Bread, reduced calorie and/or high fiber, white or NFS, toasted	3	50
51122050	Bread, reduced calorie and/or high fiber, Italian	3	50
51122100	Bread, reduced calorie and/or high fiber, white or NFS, with fruit and/or nuts	3	50
51122300	Bread, white, special formula, added fiber	3	50
51123010	Bread, high protein	3	50
51152000	Roll, white, soft, reduced calorie and/or high fiber	3	50
51161030	Roll, sweet, with fruit, frosted, diet	3	55
51161070	Roll, sweet, with fruit, frosted, fat free	3	55
51165100	Coffee cake, yeast type, fat free, cholesterol free, with fruit	3	55
51180010	Bagel	3	55
51180020	Bagel, toasted	3	55
51180030	Bagel, with raisins	3	55
51180080	Bagel, with fruit other than raisins	3	55
51184100	Bread stick, hard, low sodium	3	30
51201010	Bread, whole wheat, 100%	3	50
51201020	Bread, whole wheat, 100%, toasted	3	50
51201060	Bread, whole wheat, 100%, made from home recipe or purchased at bakery	3	50
51201070	Bread, whole wheat, 100%, made from home recipe or purchased at bakery, toasted	3	50
51201120	Bread, whole wheat, 100%, with raisins, toasted	3	50
51201150	Bread, pita, whole wheat, 100%	3	50

Food Code	Baked Goods: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
51207010	Bread, sprouted wheat	3	50
51207020	Bread, sprouted wheat, toasted	3	50
51208100	Bagel, whole wheat, 100%, with raisins	3	55
51220000	Roll, whole wheat, 100%	3	50
51300050	Bread, whole grain white	3	50
51300110	Bread, whole wheat, NS as to 100%	3	50
51300120	Bread, whole wheat, NS as to 100%, toasted	3	50
51300180	Bread, puri or poori (Indian puffed bread), whole wheat, NS as to 100%, fried	3	50
51300210	Bread, whole wheat, NS as to 100%, with raisins	3	50
51300220	Bread, whole wheat, NS as to 100%, with raisins, toasted	3	50
51301010	Bread, wheat or cracked wheat	3	50
51301020	Bread, wheat or cracked wheat, toasted	3	50
51301120	Bread, wheat or cracked wheat, with raisins	3	50
51301510	Bread, wheat or cracked wheat, reduced calorie and/or high fiber	3	50
51301520	Bread, wheat or cracked wheat, reduced calorie and/or high fiber, toasted	3	50
51301540	Bread, French or Vienna, whole wheat, NS as to 100%, made from home recipe or purchased at bakery	3	50
51301600	Bread, pita, whole wheat, NS as to 100%	3	50
51301620	Bread, pita, wheat or cracked wheat	3	50
51301700	Bagel, wheat	3	55
51301750	Bagel, whole wheat, NS as to 100%	3	55
51301800	Bagel, wheat, with raisins	3	55
51301820	Bagel, wheat, with fruit and nuts	3	55
51301900	Bagel, wheat bran	3	55
51302020	Bread, wheat bran, toasted	3	50
51302050	Bread, wheat bran, with raisins	3	50
51302060	Bread, wheat bran, with raisins, toasted	3	50
51302500	Muffin, English, wheat bran	3	50
51302520	Muffin, English, wheat bran, with raisins	3	50
51303010	Muffin, English, wheat or cracked wheat	3	50
51303030	Muffin, English, whole wheat, NS as to 100%	3	50
51303050	Muffin, English, wheat or cracked wheat, with raisins	3	50
51303070	Muffin, English, whole wheat, NS as to 100%, with raisins	3	50
51320010	Roll, wheat or cracked wheat	3	50
51320020	Roll, wheat or cracked wheat, toasted	3	50
51320500	Roll, whole wheat, NS as to 100%	3	50
51320530	Roll, whole wheat, NS as to 100%, made from home recipe or purchased	3	50

Food Code	Baked Goods: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
	at bakery		
51601010	Bread, multigrain, toasted	3	50
51601020	Bread, multigrain	3	50
51601210	Bread, multigrain, with raisins	3	50
51601220	Bread, multigrain, with raisins, toasted	3	50
51602010	Bread, multigrain, reduced calorie and/or high fiber	3	50
51620000	Roll, multigrain	3	50
51630000	Bagel, multigrain	3	55
51630100	Bagel, multigrain, with raisins	3	55
51630200	Muffin, English, multigrain	3	50
51804020	Bread, soy, toasted	3	50
52104040	Biscuit, whole wheat	3	55
52215200	Tortilla, flour (wheat)	3	55
52215260	Tortilla, whole wheat	3	55
52301000	Muffin, NFS	3	55
52302020	Muffin, fruit and/or nut, low fat	3	55
52302100	Muffin, fruit, fat free, cholesterol free	3	55
52303010	Muffin, whole wheat	3	55
52303500	Muffin, wheat	3	55
52304010	Muffin, wheat bran	3	55
52304040	Muffin, bran with fruit, lowfat	3	55
52304060	Muffin, bran with fruit, no fat, no cholesterol	3	55
52304150	Muffin, oat bran	3	55
52304200	Muffin, oat bran with fruit and/or nuts	3	55
53102300	Cake, applesauce, diet, without icing	3	80
53104300	Cake, carrot, diet	3	125
53104520	Cheesecake, diet	3	125
53104570	Cheesecake, diet, with fruit	3	125
53105500	Cake, chocolate, with icing, diet	3	80
53105750	Cake, chocolate, devil's food, or fudge, pudding type mix, made by "cholesterol free" recipe (water, oil and egg whites added to dry mix), with "light" icing, coating or filling	3	80
53109210	Cake, cupcake, not chocolate, with icing or filling, lowfat, cholesterol free	3	80
53109270	Cake, cupcake, chocolate, with or without icing, fruit filling or cream filling, lowfat, cholesterol free	3	80
53114200	Cake, lemon, lowfat, without icing	3	80
53114250	Cake, lemon, lowfat, with icing	3	80
53116390	Cake, pound, reduced fat, cholesterol free	3	80

Food Code	Baked Goods: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
53120500	Cake, whole wheat, with fruit and nuts, without icing	3	125
53123500	Cake, shortcake, with whipped topping and fruit, diet	3	125
53204830	Cookie, brownie, lowfat, with icing	3	30
53204840	Cookie, brownie, lowfat, without icing	3	30
53204850	Cookie, brownie, fat free, cholesterol free, with icing	3	30
53204860	Cookie, brownie, fat free, without icing	3	30
53206030	Cookie, chocolate chip, reduced fat	3	30
53207050	Cookie, chocolate, with chocolate filling or coating, fat free	3	30
53209020	Cookie, chocolate sandwich, reduced fat	3	30
53220010	Cookie, fruit-filled bar, fat free	3	30
53220040	Cookie, fig bar, fat free	3	30
53231400	Cookie, multigrain, high fiber	3	30
53233030	Cookie, oatmeal, fat free, with raisins	3	30
53233040	Cookie, oatmeal, reduced fat, with raisins	3	30
53239010	Cookie, shortbread, reduced fat	3	30
53243050	Cookie, vanilla sandwich, reduced fat	3	30
53260030	Cookie, dietetic, chocolate chip	3	30
53260150	Cookie, lemon wafer, lowfat	3	30
53260200	Cookie, dietetic, oatmeal with raisins	3	30
53260300	Cookie, dietetic, sandwich type	3	30
53260400	Cookie, dietetic, sugar or plain	3	30
53300100	Pie, NFS	3	125
53300170	Pie, individual size or tart, NFS	3	125
53301750	Pie, apple, diet	3	125
53366000	Pie, yogurt, frozen	3	125
53420210	Cream puff, eclair, custard or cream filled, iced, reduced fat	3	80
55101010	Pancakes, reduced calorie, high fiber	3	110
55105000	Pancakes, buckwheat	3	110
55105200	Pancakes, whole wheat	3	110
55202000	Waffle, wheat, bran, or multigrain	3	85
55205000	Waffle, 100% whole wheat or 100% whole grain	3	85
55206000	Waffle, oat bran	3	85
55211000	Waffle, plain, fat free	3	85
55211050	Waffle, plain, lowfat	3	85
27540230*	Chicken patty sandwich with cheese, on wheat bun, with lettuce, tomato and spread	3	50*
27540240*	Chicken fillet, (broiled), sandwich, on whole wheat roll, with lettuce, tomato and spread	3	50*

Food Code	Baked Goods: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
27540250*	Chicken fillet, broiled, sandwich with cheese, on whole wheat roll, with lettuce, tomato and non-mayonaise type spread	3	50*

*Only the breading portion of the food was included in the analysis and the serving size of bread (50g) was used to estimate the EDI of resistant dextrin rather than the entire sandwich serving size (195g).

Beverages- Liquid Non Dairy

Food Code	Beverages- Liquid Non-Dairy: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
64100100	Fruit juice, NFS	3	240
64100110	Fruit juice blend, 100% juice, with added Vitamin C	3	240
64100200	Fruit juice blend, with cranberry, 100% juice	3	240
74301100	Tomato juice	3	240
74301150	Tomato juice, low sodium	3	240
74302000	Tomato juice cocktail	3	240
74303000	Tomato and vegetable juice, mostly tomato	3	240
74304000	Tomato juice with clam or beef juice	3	240
92100000	Coffee, NS as to type	3	240
92100500	Coffee, regular, NS as to ground or instant	3	240
92101000	Coffee, made from ground, regular	3	240
92101500	Coffee, made from ground, equal parts regular and decaffeinated	3	240
92101600	Coffee, Turkish	3	240
92101610	Coffee, espresso	3	240
92101630	Coffee, espresso, decaffeinated	3	240
92101700	Coffee, made from ground, regular, flavored	3	240
92101800	Coffee, Cuban	3	240
92101900	Coffee, latte	3	240
92101910	Coffee, latte, decaffeinated	3	240
92101920	Frappuccino, regular	3	240
92101930	Frappuccino, decaffeinated	3	240
92101950	Coffee, mocha	3	240
92152000	Coffee and chicory, made from ground	3	240
92161000	Cappuccino	3	240
92162000	Cappuccino, decaffeinated	3	240
92201010	Postum	3	240
92301000	Tea, NS as to type, unsweetened	3	240
92301060	Tea, NS as to type, presweetened with sugar	3	240

Food Code	Beverages- Liquid Non-Dairy: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
92301080	Tea, NS as to type, presweetened with low calorie sweetener	3	240
92301100	Tea, NS as to type, decaffeinated, unsweetened	3	240
92301130	Tea, NS as to type, presweetened, NS as to sweetener	3	240
92301160	Tea, NS as to type, decaffeinated, presweetened with sugar	3	240
92301180	Tea, NS as to type, decaffeinated, presweetened with low calorie sweetener	3	240
92301190	Tea, NS as to type, decaffeinated, presweetened, NS as to sweetener	3	240
92304000	Tea, made from frozen concentrate, unsweetened	3	240
92305000	Tea, made from powdered instant, presweetened, NS as to sweetener	3	240
92305010	Tea, made from powdered instant, unsweetened	3	240
92305040	Tea, made from powdered instant, presweetened with sugar	3	240
92305050	Tea, made from powdered instant, decaffeinated, presweetened with sugar	3	240
92306000	Tea, herbal	3	240
92306020	Tea, herbal, presweetened with sugar	3	240
92306030	Tea, herbal, presweetened with low calorie sweetener	3	240
92306040	Tea, herbal, presweetened, NS as to sweetener	3	240
92410110	Carbonated water, sweetened	3	240
92410210	Carbonated water, unsweetened	3	240
92410250	Carbonated water, sugar-free	3	240
92431000	Carbonated juice drink, NS as to type of juice	3	240
92433000	Carbonated noncitrus juice drink	3	240
92512040	Frozen daiquiri mix, frozen concentrate, not reconstituted	3	70
92512050	Frozen daiquiri mix, from frozen concentrate, reconstituted	3	240
92520410	Fruit drink, low calorie	3	240
92520910	Lemonade, low calorie	3	240
92530310	Cherry drink with vitamin C added	3	240
92530410	Citrus drink with vitamin C added	3	240
92530510	Cranberry juice drink with vitamin C added	3	240
92530520	Cranberry-apple juice drink with vitamin C added	3	240
92530610	Fruit punch, fruit drink, or fruitade, with vitamin C added	3	240
92530810	Grapefruit juice drink with vitamin C added	3	240
92530840	Guava juice drink with vitamin C added	3	240
92530910	Lemonade with vitamin C added	3	240
92530950	Vegetable and fruit juice drink, with vitamin C added	3	240
92531010	Orange drink and orangeade with vitamin C added	3	240
92531030	Fruit juice drink, with thiamin (vitamin B1) and vitamin C	3	240
92541010	Fruit-flavored drink, made from sweetened powdered mix (fortified	3	240

Food Code	Beverages- Liquid Non-Dairy: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
	with vitamin C)		
92541100	Apple cider-flavored drink, made from powdered mix, with sugar and vitamin C added	3	240
92542000	Fruit-flavored drink, made from powdered mix, mainly sugar, with high vitamin C added	3	240
92544000	Fruit-flavored drink, made from unsweetened powdered mix (fortified with vitamin C), with sugar added in preparation	3	240
92550030	Fruit juice drink, low calorie	3	240
92550050	Apple-white grape juice drink, low calorie, with vitamin C added	3	240
92550110	Cranberry juice drink, low calorie, with vitamin C added	3	240
92550210	Cranberry-apple juice drink, low calorie, with vitamin C added	3	240
92550300	Grapefruit juice drink, low calorie, with vitamin C added	3	240
92550610	Fruit-flavored drinks, punches, ades, low calorie, with vitamin C added	3	240
92550620	Fruit flavored drink, low calorie	3	240
92551700	Juice drink, low calorie	3	240
92552020	Fruit juice drink, reduced sugar, with thiamin (vitamin B1) and vitamin C	3	240
92552100	Orange-cranberry juice drink, low calorie, with vitamin C added	3	240
92553000	Fruit-flavored thirst quencher beverage, low calorie	3	240
92560000	Fruit-flavored thirst quencher beverage	3	240
92560100	Gatorade Thirst Quencher sports drink	3	240
92560200	Powerade sports drink	3	240
92582100	Citrus juice drink, calcium fortified	3	240
92582110	Fruit juice drink, with thiamin (vitamin B1) and vitamin C plus calcium	3	240
92650000	Red Bull Energy Drink	3	240
92651000	Energy drink	3	240
93102000	Beer, lite	3	240
94100100	Water, bottled, unsweetened	3	240
94100200	Water, bottled, sweetened, with low or no calorie sweetener	3	240
94210100	Propel Fitness Water	3	240
94210200	Vitamin Water	3	240

Cereals and Granola Bars

Food Code	Cereals and Granola Bars: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
53530010	Breakfast tart, lowfat	6	55

Food Code	Cereals and Granola Bars: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
53540000	Breakfast bar, NFS	6	40
53540200	Breakfast bar, cereal crust with fruit filling, lowfat	6	40
53540250	Breakfast bar, cereal crust with fruit filling, fat free	6	40
53540500	Breakfast bar, date, with yogurt coating	6	40
53540600	Milk 'n Cereal bar	6	40
53540700	Kellogg's Special K bar	6	40
53541200	Meal replacement bar	6	40
53542100	Granola bar, oats, sugar, raisins, coconut	6	40
53542200	Granola bar, oats, fruit and nuts, lowfat	6	40
53542210	Granola bar, nonfat	6	40
53543100	Granola bar, peanuts, oats, sugar, wheat germ	6	40
53544200	Granola bar, chocolate-coated	6	40
53544220	Granola bar with nuts, chocolate-coated	6	40
53544250	Granola bar, coated with non-chocolate coating	6	40
53544300	Granola bar, high fiber, coated with non-chocolate yogurt coating	6	40
53544450	PowerBar (fortified high energy bar)	6	40
56200300	Cereal, cooked, NFS	6	240
56200350	Cereal, cooked, instant, NS as to grain	6	240
56200990	Grits, cooked, corn or hominy, NS as to regular, quick or instant, NS as to fat added in cooking	6	240
56201000	Grits, cooked, corn or hominy, NS as to regular, quick, or instant, fat not added in cooking	6	240
56201010	Grits, cooked, corn or hominy, regular, fat not added in cooking	6	240
56201020	Grits, cooked, corn or hominy, regular, fat added in cooking	6	240
56201030	Grits, cooked, corn or hominy, regular, NS as to fat added in cooking	6	240
56201040	Grits, cooked, corn or hominy, NS as to regular, quick, or instant, fat added in cooking	6	240
56201060	Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, NS as to fat added in cooking	6	240
56201062	Grits, cooked, corn or hominy, with cheese, NS as to regular, quick, or instant, fat added in cooking	6	240
56201070	Grits, cooked, corn or hominy, with cheese, regular, NS as to fat added in cooking	6	240
56201071	Grits, cooked, corn or hominy, with cheese, regular, fat not added in cooking	6	240
56201072	Grits, cooked, corn or hominy, with cheese, regular, fat added in cooking	6	240
56201082	Grits, cooked, corn or hominy, with cheese, quick, fat added in cooking	6	240
56201091	Grits, cooked, corn or hominy, with cheese, instant, fat not added in cooking	6	240
56201092	Grits, cooked, corn or hominy, with cheese, instant, fat added in cooking	6	240
56201110	Grits, cooked, corn or hominy, quick, fat not added in cooking	6	240

Food Code	Cereals and Granola Bars: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
56201120	Grits, cooked, corn or hominy, quick, fat added in cooking	6	240
56201130	Grits, cooked, corn or hominy, quick, NS as to fat added in cooking	6	240
56201210	Grits, cooked, corn or hominy, instant, fat not added in cooking	6	240
56201220	Grits, cooked, corn or hominy, instant, fat added in cooking	6	240
56201230	Grits, cooked, corn or hominy, instant, NS as to fat added in cooking	6	240
56201240	Grits, cooked, flavored, corn or hominy, instant, fat not added in cooking	6	240
56202960	Oatmeal, cooked, NS as to regular, quick or instant; NS as to fat added in cooking	6	240
56202970	Oatmeal, cooked, quick (1 or 3 minutes), NS as to fat added in cooking	6	240
56202980	Oatmeal, cooked, regular, NS as to fat added in cooking	6	240
56203000	Oatmeal, cooked, NS as to regular, quick or instant, fat not added in cooking	6	240
56203010	Oatmeal, cooked, regular, fat not added in cooking	6	240
56203020	Oatmeal, cooked, quick (1 or 3 minutes), fat not added in cooking	6	240
56203030	Oatmeal, cooked, instant, fat not added in cooking	6	240
56203050	Oatmeal, cooked, regular, fat added in cooking	6	240
56203060	Oatmeal, cooked, quick (1 or 3 minutes), fat added in cooking	6	240
56203070	Oatmeal, cooked, instant, fat added in cooking	6	240
56203080	Oatmeal, cooked, instant, NS as to fat added in cooking	6	240
56203210	Oatmeal, NS as to regular, quick, or instant, made with milk, fat not added in cooking	6	240
56203220	Oatmeal, NS as to regular, quick, or instant, made with milk, fat added in cooking	6	240
56203230	Oatmeal, NS as to regular, quick, or instant, made with milk, NS as to fat added in cooking	6	240
56203610	Oatmeal, multigrain, cooked, fat not added in cooking	6	240
56206990	Wheat, cream of, cooked, NS as to regular, quick, or instant, NS as to fat added in cooking	6	240
56207000	Wheat, cream of, cooked, NS as to regular, quick, or instant, fat not added in cooking	6	240
56207010	Wheat, cream of, cooked, regular, fat not added in cooking	6	240
56207020	Wheat, cream of, cooked, quick, fat not added in cooking	6	240
56207030	Wheat, cream of, cooked, instant, fat not added in cooking	6	240
56207040	Wheat, cream of, cooked, made with milk	6	240
56207060	Wheat, cream of, cooked, instant, fat added in cooking	6	240
56207080	Wheat, cream of, cooked, NS as to regular, quick, or instant, fat added in cooking	6	240
56207200	Whole wheat cereal, cooked, fat not added in cooking	6	240
56207220	Wheat, cream of, cooked, regular, fat added in cooking	6	240
56207230	Wheat, cream of, cooked, quick, fat added in cooking	6	240
56207300	Whole wheat cereal, wheat and barley, cooked, fat not added in cooking	6	240

Food Code	Cereals and Granola Bars: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
56207330	Whole wheat cereal, wheat and barley, cooked, fat added in cooking	6	240
56207360	Wheat cereal, chocolate flavored, cooked, fat not added in cooking	6	240
56207370	Wheat cereal, chocolate flavored, cooked, NS as to fat added in cooking	6	240
56208500	Oat bran cereal, cooked, fat not added in cooking	6	240
56208510	Oat bran cereal, cooked, fat added in cooking	6	240
56210000	Nestum cereal	6	240
57000000	Cereal, NFS	6	55
57000050	Kashi cereal, NS as to ready to eat or cooked	6	30
57000100	Oat cereal, NFS	6	30
57100100	Cereal, ready-to-eat, NFS	6	30
57100400	Character cereals, TV or movie, General Mills	6	30
57100500	Character cereals, TV or movie, Kelloggs	6	30
57101000	All-Bran	6	55
57101020	All-Bran with Extra Fiber	6	55
57102000	Alpen	6	55
57103000	Alpha-Bits	6	55
57103050	Amaranth Flakes	6	30
57103100	Apple Cinnamon Cheerios	6	30
57103500	Apple Cinnamon Squares Mini-Wheats, Kellogg's (formerly Apple Cinnamon Squares)	6	55
57104000	Apple Jacks	6	30
57106050	Banana Nut Crunch Cereal (Post)	6	55
57106100	Basic 4	6	55
57106250	Berry Berry Kix	6	30
57106260	Berry Burst Cheerios	6	30
57106530	Blueberry Morning, Post	6	55
57107000	Booberry	6	30
57110000	All-Bran Bran Buds, Kellogg's (formerly Bran Buds)	6	55
57111000	Bran Chex	6	55
57117000	Cap'n Crunch	6	30
57117500	Cap'n Crunch's Christmas Crunch	6	30
57119000	Cap'n Crunch's Crunch Berries	6	30
57120000	Cap'n Crunch's Peanut Butter Crunch	6	30
57123000	Cheerios	6	30
57124000	Chex cereal, NFS	6	30
57124200	Chocolate flavored frosted puffed corn cereal	6	30
57124500	Cinnamon Grahams, General Mills	6	30

Food Code	Cereals and Granola Bars: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
57125000	Cinnamon Toast Crunch	6	30
57125900	Honey Nut Clusters (formerly called Clusters)	6	55
57126000	Cocoa Krispies	6	30
57127000	Cocoa Pebbles	6	30
57128000	Cocoa Puffs	6	30
57128880	Complete Oat Bran Flakes, Kellogg's (formerly Common Sense Oat Bran, plain)	6	30
57130000	Cookie-Crisp	6	30
57131000	Crunchy Corn Bran, Quaker	6	30
57132000	Corn Chex	6	30
57134000	Corn flakes, NFS	6	30
57135000	Corn flakes, Kellogg	6	30
57137000	Corn Puffs	6	15
57138000	Total Corn Flakes	6	30
57139000	Count Chocula	6	30
57143000	Cracklin' Oat Bran	6	55
57143500	Cranberry Almond Crunch, Post	6	55
57144000	Crisp Crunch	6	30
57148000	Crispix	6	30
57148500	Crispy Brown Rice Cereal	6	30
57151000	Crispy Rice	6	30
57152000	Crispy Wheats'n Raisins	6	55
57201800	Disney cereals, Kellogg's	6	30
57206000	Familia	6	55
57206700	Fiber One	6	55
57206800	Fiber 7 Flakes, Health Valley	6	30
57207000	Bran Flakes, NFS (formerly 40% Bran Flakes, NFS)	6	55
57208000	Complete Wheat Bran Flakes, Kellogg's (formerly 40% Bran Flakes)	6	30
57209000	Natural Bran Flakes, Post (formerly called 40% Bran Flakes, Post)	6	30
57211000	Frankenberry	6	30
57212100	French Toast Crunch, General Mills	6	30
57213000	Froot Loops	6	30
57213850	Frosted Cheerios	6	30
57214000	Frosted Mini-Wheats	6	55
57214100	Frosted Wheat Bites	6	55
57215000	Frosty O's	6	30
57218000	Frosted Rice Krispies	6	30

Food Code	Cereals and Granola Bars: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
57219000	Fruit & Fibre (fiber), NFS	6	55
57221000	Fruit & Fibre (fiber) with dates, raisins, and walnuts	6	55
57221650	Fruit Harvest cereal, Kellogg's	6	30
57221700	Fruit Rings, NFS	6	30
57223000	Fruity Pebbles	6	30
57224000	Golden Grahams	6	30
57227000	Granola, NFS	6	55
57228000	Granola, homemade	6	55
57229000	Granola, lowfat, Kellogg's	6	55
57229500	Granola with Raisins, lowfat, Kellogg's	6	55
57230000	Grape-Nuts	6	55
57231000	Grape-Nut Flakes	6	30
57231200	Great Grains, Raisin, Date, and Pecan Whole Grain Cereal, Post	6	55
57231250	Great Grains Double Pecan Whole Grain Cereal, Post	6	55
57232100	Healthy Choice Almond Crunch with raisins, Kellogg's	6	55
57237100	Honey Bunches of Oats	6	30
57237300	Honey Bunches of Oats with Almonds, Post	6	30
57238000	Honeycomb, plain	6	30
57239000	Honeycomb, strawberry	6	30
57239100	Honey Crunch Corn Flakes, Kellogg's	6	30
57240100	Honey Nut Chex	6	30
57241000	Honey Nut Cheerios	6	30
57241200	Honey Nut Shredded Wheat, Post	6	55
57243000	Smacks, Kellogg's (formerly Honey Smacks)	6	30
57245000	Just Right Fruit and Nut (formerly Just Right with raisins, dates, and nuts)	6	55
57301100	Kaboom	6	30
57301500	Kashi, Puffed	6	30
57301510	Kashi GoLean	6	55
57301511	Kashi GoLean Crunch	6	55
57301520	Kashi Good Friends	6	55
57301530	Kashi Heart to Heart	6	55
57302100	King Vitaman	6	30
57303100	Kix	6	30
57304100	Life (plain and cinnamon)	6	55
57305100	Lucky Charms	6	30
57305150	Frosted oat cereal with marshmallows	6	30

Food Code	Cereals and Granola Bars: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
57305170	Malt-O-Meal Coco-Roos	6	30
57305180	Malt-O-Meal Corn Bursts	6	30
57305210	Malt-O-Meal Frosted Flakes	6	30
57305500	Malt-O-Meal Honey and Nut Toasty O's	6	30
57305600	Malt-O-Meal Marshmallow Mateys	6	30
57306100	Malt-O-Meal Puffed Rice	6	15
57306120	Malt-O-Meal Puffed Wheat	6	15
57306500	Malt-O-Meal Golden Puffs (formerly Sugar Puffs)	6	30
57306700	Malt-O-Meal Toasted Oat Cereal	6	30
57306800	Malt-O-meal Tootie Fruities	6	30
57307150	Marshmallow Safari, Quaker	6	30
57307500	Millet, puffed	6	30
57308150	Mueslix cereal, NFS	6	55
57308190	Muesli with raisins, dates, and almonds	6	55
57308300	Multi Bran Chex	6	55
57308400	Multi Grain Cheerios	6	30
57309100	Nature Valley Granola, with fruit and nuts	6	55
57316200	Nutty Nuggets, Ralston Purina	6	55
57316300	Oat Bran Flakes, Health Valley	6	30
57316410	Apple Cinnamon Oatmeal Crisp (formerly Oatmeal Crisp with Apples)	6	55
57316450	Oatmeal Crisp with Almonds	6	55
57316500	Oatmeal Raisin Crisp	6	55
57316710	Oh's, Honey Graham	6	30
57316750	Oh's, Fruitangy, Quaker	6	55
57318000	100% Bran	6	30
57319000	100% Natural Cereal, plain, Quaker	6	55
57319500	Sun Country 100% Natural Granola, with Almonds	6	55
57320500	100 % Natural Cereal, with oats, honey and raisins, Quaker	6	55
57321500	100 % Natural Wholegrain Cereal with raisins, lowfat, Quaker	6	55
57321700	Optimum, Nature's Path	6	55
57321800	Optimum Slim, Nature's Path	6	55
57322500	Oreo O's cereal, Post	6	30
57323000	Sweet Crunch, Quaker (formerly called Popeye)	6	30
57323050	Sweet Puffs, Quaker	6	55
57325000	Product 19	6	30
57327450	Quaker Oat Bran Cereal	6	55

Food Code	Cereals and Granola Bars: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
57327500	Quaker Oatmeal Squares (formerly Quaker Oat Squares)	6	55
57329000	Raisin bran, NFS	6	55
57330000	Raisin Bran, Kellogg	6	55
57330010	Raisin Bran Crunch, Kellogg's	6	55
57331000	Raisin Bran, Post	6	55
57332050	Raisin Bran, Total	6	55
57332100	Raisin Nut Bran	6	55
57335550	Reese's Peanut Butter Puffs cereal	6	30
57336000	Rice Chex	6	55
57337000	Rice Flakes, NFS	6	30
57339000	Rice Krispies	6	30
57339500	Rice Krispies Treats Cereal (Kellogg's)	6	30
57340000	Rice, puffed	6	30
57340700	Scooby Doo Cinnamon Marshmallow Cereal, Kellogg's	6	30
57341000	Shredded Wheat'N Bran	6	55
57341200	Smart Start, Kellogg's	6	55
57342010	Smorz, Kellogg's	6	30
57344000	Special K	6	55
57344010	Special K Red Berries	6	30
57344020	Special K Vanilla Almond	6	30
57346500	Oatmeal Honey Nut Heaven, Quaker (formerly Toasted Oatmeal, Honey Nut)	6	55
57347000	Corn Pops	6	30
57347500	Strawberry Squares Mini-Wheats, Kellogg's (formerly Strawberry Squares)	6	55
57348000	Frosted corn flakes, NFS	6	55
57349000	Frosted Flakes, Kellogg	6	55
57355000	Golden Crisp (Formerly called Super Golden Crisp)	6	55
57401100	Toasted oat cereal	6	30
57403100	Toasties, Post	6	30
57404100	Malt-O-Meal Toasty O's	6	30
57404200	Malt-O-Meal Apple and Cinnamon Toasty O's	6	30
57406100	Total	6	30
57407100	Trix	6	30
57408100	Uncle Sam's Hi Fiber Cereal	6	30
57409100	Waffle Crisp, Post	6	30
57410000	Weetabix Whole Wheat Cereal	6	55

Food Code	Cereals and Granola Bars: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
57411000	Wheat Chex	6	55
57412000	Wheat germ, plain	6	55
57416000	Wheat, puffed, plain	6	30
57416010	Wheat, puffed, presweetened with sugar	6	30
57417000	Shredded Wheat, 100%	6	30
57418000	Wheaties	6	30
57601100	Wheat bran, unprocessed	6	15
57602100	Oats, raw	6	40
57602500	Oat bran, uncooked	6	15

Condiments and Dressings

Food Code	Condiments and Dressings: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
41420350	Soy sauce, reduced sodium	3	15
41420410	Teriyaki sauce, reduced sodium	3	15
74401010	Tomato catsup	3	15
74406010	Barbecue sauce	3	30
75506100	Mustard sauce	3	30
83110010	Mayonnaise-type salad dressing, cholesterol-free	3	15
83200100	Salad dressing, low-calorie, NFS	3	30
83201000	Blue or roquefort cheese dressing, low-calorie	3	30
83201050	Blue or roquefort cheese dressing, reduced calorie	3	30
83201200	Blue or roquefort cheese dressing, reduced calorie, fat-free, cholesterol-free	3	30
83202000	French dressing, low-calorie	3	30
83202010	French dressing, reduced calorie, fat-free, cholesterol-free	3	30
83202020	French dressing, reduced calorie	3	30
83203000	Caesar dressing, low-calorie	3	30
83203250	Mayonnaise-type salad dressing, fat-free	3	15
83204000	Mayonnaise, low-calorie or diet	3	15
83204020	Mayonnaise, reduced calorie or diet, cholesterol-free	3	15
83204050	Mayonnaise-type salad dressing, low-calorie or diet	3	15
83204060	Mayonnaise-type salad dressing, low-calorie or diet, cholesterol-free	3	15
83204500	Honey mustard dressing, reduced calorie	3	30
83205000	Italian dressing, low calorie	3	30
83205450	Italian dressing, reduced calorie	3	30

Food Code	Condiments and Dressings: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
83205500	Italian dressing, reduced calorie, fat-free	3	30
83206000	Russian dressing, low-calorie	3	30
83207000	Thousand Island dressing, low-calorie	3	30
83207100	Thousand Island dressing, reduced calorie, fat-free, cholesterol-free	3	30
83208000	Vinegar, sugar, and water dressing	3	30
83210000	Creamy dressing, made with sour cream and/or buttermilk and oil, diet, NS as to low or reduced calorie	3	30
83210100	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie	3	30
83210200	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie, fat-free, cholesterol-free	3	30
83210250	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie, cholesterol-free	3	30
83220000	Salad dressing, low calorie, oil-free	3	30
91300010	Syrup, NFS	3	60
91300100	Pancake syrup, NFS	3	60
91301060	Maple syrup (100% maple)	3	60
91301080	Chocolate syrup, thin type	3	30
91301081	Chocolate syrup, thin type, light	3	30
91301250	Maple and corn and/or cane pancake syrup blends (formerly Corn and maple syrup (2% maple))	3	60
91301510	Syrup, pancake, reduced calorie	3	60
91304010	Topping, butterscotch or caramel	3	30
91304020	Topping, chocolate, thick, fudge type	3	30
91305010	Icing, chocolate	3	35
91305020	Icing, white	3	35
91351010	Syrup, dietetic	3	60
91351020	Topping, dietetic	3	30
91401000	Jelly, all flavors	3	15
91402000	Jam, preserves, all flavors	3	15
91403000	Fruit butter, all flavors	3	15
91404000	Marmalade, all flavors	3	15
91405000	Jelly, dietetic, all flavors, sweetened with artificial sweetener	3	15
91405500	Jelly, reduced sugar, all flavors	3	15
91406000	Jams, preserves, marmalades, dietetic, all flavors, sweetened with artificial sweetener	3	15
91406500	Jams, preserves, marmalades, sweetened with fruit juice concentrates, all flavors	3	15
91406600	Jams, preserves, marmalades, low sugar (all flavors)	3	15

Confection

Food Code	Confection: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
91700010	Candy, NFS	3	40
91703080	Caramel, all flavors, sugar free	3	40
91708100	Fruit snack candy, with added vitamin C	3	40
91770000	Dietetic or low calorie candy, NFS	3	15
91770010	Dietetic or low calorie gumdrops	3	15
91770020	Dietetic or low calorie hard candy	3	15
91770030	Dietetic or low calorie candy, chocolate covered	3	40
91770050	Dietetic or low calorie mints	3	2

Dairy Beverages

Food Code	Dairy Beverages: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
11111170	Milk, calcium fortified, cow's, fluid, skim or nonfat	3	240
11112000	Milk, cow's, fluid, other than whole, NS as to 2%, 1%, or skim (formerly milk, cow's, fluid, "lowfat", NS as to percent fat)	3	240
11113000	Milk, cow's, fluid, skim or nonfat, 0.5% or less butterfat	3	240
11114320	Milk, cow's, fluid, lactose reduced, nonfat	3	240
11511300	Milk, chocolate, skim milk-based	3	240
11511400	Milk, chocolate, lowfat milk-based	3	240
11513200	Cocoa and sugar mixture, lowfat milk added	3	240
11513300	Cocoa and sugar mixture, skim milk added	3	240
11513400	Chocolate syrup, milk added, NS as to type of milk	3	240
11513600	Chocolate syrup, lowfat milk added	3	240
11513700	Chocolate syrup, skim milk added	3	240
11541000	Milk shake, NS as to flavor or type	3	240
11541500	Milk shake, made with skim milk, chocolate	3	240
11541510	Milk shake, made with skim milk, flavors other than chocolate	3	240
11553100	Fruit smoothie drink, NFS	3	240
12100100	Cream, NS as to light, heavy, or half and half	3	32
12110100	Cream, light, fluid	3	32
12110300	Cream, light, whipped, unsweetened	3	32
12120110	Cream, half and half, fat free	3	30

Dairy Non-Beverages

Food Code	Dairy Non-Beverages: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
11422000	Yogurt, vanilla, lemon, maple, or coffee flavor, lowfat milk	3	225
11423000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk	3	225
11424000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk, sweetened with low calorie sweetener	3	225
11427000	Yogurt, chocolate, nonfat milk	3	225
11430000	Yogurt, fruit variety, NS as to type of milk	3	225
11432000	Yogurt, fruit variety, lowfat milk	3	225
11432500	Yogurt, fruit variety, lowfat milk, sweetened with low-calorie sweetener	3	225
11433000	Yogurt, fruit variety, nonfat milk	3	225
11433500	Yogurt, fruit variety, nonfat milk, sweetened with low-calorie sweetener	3	225
11445000	Yogurt, fruit and nuts, lowfat milk	3	225
12310300	Sour cream, reduced fat	3	30
12310350	Sour cream, light	3	30
12310370	Sour cream, fat free	3	30
12350020	Dip, sour cream base, reduced calorie	3	30
14010000	Cheese, NFS	3	30
14104015	Cheese, natural, Cheddar or American type, reduced fat	3	30
14106500	Cheese, Monterey, lowfat	3	30
14107010	Cheese, Mozzarella, NFS	3	30
14107030	Cheese, Mozzarella, part skim	3	30
14107060	Cheese, Mozzarella, nonfat or fat free	3	30
14107250	Cheese, Muenster, lowfat	3	30
14108015	Cheese, Parmesan, dry grated, reduced fat	3	5
14108060	Parmesan cheese topping, fat free	3	30
14109030	Cheese, Swiss, lowfat	3	30
14110030	Cheese, Cheddar or Colby, lowfat	3	30
14120020	Cheese, Mexican blend, reduced fat	3	30
14204010	Cheese, cottage, lowfat (1-2% fat)	3	110
14204020	Cheese, cottage, lowfat, with fruit	3	110
14303010	Cheese, cream, light or lite (formerly called Cream Cheese Lowfat)	3	30
14410300	Cheese, processed, American or Cheddar type, lowfat	3	30
14410330	Cheese, processed cheese product, American or Cheddar type, reduced fat	3	30
14410350	Cheese, processed, American or Cheddar type, nonfat or fat free	3	30
14410380	Cheese, processed cream cheese product, nonfat or fat free	3	30
14410420	Cheese, processed, Swiss, lowfat	3	30
14420210	Cheese spread, cream cheese, light or lite	3	30

Dry Beverage Powder

Food Code	Dry Beverage Powder: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
11514300	Cocoa with nonfat dry milk and low calorie sweetener, mixture, water added	3	240
11514500	Cocoa, whey, and low calorie sweetener, mixture, fortified, water added	3	240
11516000	Cocoa, whey, and low-calorie sweetener mixture, lowfat milk added	3	240
11830110	Cocoa powder with nonfat dry milk and low calorie sweetener, dry mix, not reconstituted	9	34
11830120	Cocoa, whey, and low calorie sweetener, fortified, dry mix, not reconstituted	9	34
11830150	Cocoa powder, not reconstituted (no dry milk)	9	34
11830170	Cocoa, whey, and low-calorie sweetener mixture, not reconstituted	9	34
92103000	Coffee, made from powdered instant, regular	3	240
92104000	Coffee, made from powdered instant, 50% less caffeine	3	240
92106000	Coffee, acid neutralized, from powdered instant	3	240
92111000	Coffee, decaffeinated, NS as to ground or instant	3	240
92114000	Coffee, decaffeinated, made from powdered instant	3	240
92121000	Coffee, made from powdered instant mix, with whitener and sugar, instant	3	240
92121010	Coffee, made from powdered instant mix, presweetened, no whitener	3	240
92121020	Coffee and cocoa (mocha), made from powdered instant mix, with whitener, presweetened	3	240
92121030	Coffee and cocoa (mocha), made from powdered instant mix, with whitener and low calorie sweetener	3	240
92121040	Coffee, made from powdered instant mix, with whitener and low calorie sweetener	3	240
92121050	Coffee and cocoa (mocha), made from powdered instant mix, with whitener and low calorie sweetener, decaffeinated	3	240
92191000	Coffee, dry instant powder, NS as to regular or decaffeinated	9	2.4
92191100	Coffee, dry instant powder, regular	9	2.4
92191200	Coffee, dry instant powder, decaffeinated	9	2.4
92192000	Coffee and cocoa (mocha) mix, dry instant powder with whitener, presweetened	9	2.4
92193000	Coffee, dry instant powder, with whitener and sugar	9	2.4
92291300	Postum, dry powder	9	240
92305090	Tea, made from powdered instant, presweetened with low calorie sweetener	3	240
92305110	Tea, made from powdered instant, decaffeinated, presweetened with low calorie sweetener	3	240
92305180	Tea, made from powdered instant, decaffeinated, unsweetened	3	240
92305800	Tea, made from powdered instant, decaffeinated, presweetened, NS as to sweetener	3	240
92307000	Tea, powdered instant, unsweetened, dry	3	240
92552000	Fruit-flavored drink, made from powdered mix with high vitamin C added, low calorie	3	240

Food Code	Dry Beverage Powder: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
92552010	Fruit flavored drink, made from powdered mix, low calorie	3	240
92731000	Fruit-flavored drink, non-carbonated, made from powdered mix, with sugar	3	240
92741000	Fruit-flavored drink, non-carbonated, made from low calorie powdered mix	3	240
92900110	Fruit-flavored concentrate, dry powder, with sugar and vitamin C added	9	21.6
92900200	Fruit-flavored beverage, dry concentrate, low calorie, not reconstituted	9	21.6

Frozen Desserts

Food Code	Frozen Desserts: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
11459990	Yogurt, frozen, NS as to flavor, NS as to type of milk	3	120
11460000	Yogurt, frozen, flavors other than chocolate, NS as to type of milk	3	120
11460150	Yogurt, frozen, NS as to flavor, lowfat milk	3	120
11460170	Yogurt, frozen, flavors other than chocolate, lowfat milk	3	120
11460250	Yogurt, frozen, flavors other than chocolate, with sorbet or sorbet-coated	3	120
11460300	Yogurt, frozen, flavors other than chocolate, nonfat milk	3	120
11460410	Yogurt, frozen, flavors other than chocolate, nonfat milk, with low-calorie sweetener	3	120
11461270	Yogurt, frozen, cone, flavors other than chocolate, lowfat milk	3	120
13130100	Light ice cream, NS as to flavor (formerly ice milk)	3	120
13130300	Light ice cream, flavors other than chocolate (formerly ice milk)	3	120
13130320	Light ice cream, no sugar added, NS as to flavor	3	120
13130330	Light ice cream, no sugar added, flavors other than chocolate	3	120
13130590	Light ice cream, soft serve, NS as to flavor (formerly ice milk)	3	120
13130600	Light ice cream, soft serve, flavors other than chocolate (formerly ice milk)	3	120
13130620	Light ice cream, soft serve cone, flavors other than chocolate (formerly ice milk)	3	120
13130700	Light ice cream, soft serve, blended with candy or cookies	3	120
13135000	Light ice cream, sandwich (formerly ice milk)	3	120
13140100	Light ice cream, bar or stick, chocolate-coated (formerly ice milk)	3	120
13140110	Light ice cream, bar or stick, chocolate covered, with nuts (formerly ice milk)	3	120
13140500	Light ice cream, cone, flavors other than chocolate (formerly ice milk)	3	120
13140650	Light ice cream, sundae, soft serve, not fruit or chocolate topping, with whipped cream (formerly ice milk)	3	240
13140660	Light ice cream, sundae, soft serve, chocolate or fudge topping (without whipped cream) (formerly ice milk)	3	240
13140670	Light ice cream, sundae, soft serve, fruit topping (without whipped cream) (formerly ice milk)	3	240

Food Code	Frozen Desserts: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
13140680	Light ice cream, sundae, soft serve, not fruit or chocolate topping (without whipped cream) (formerly ice milk)	3	240
13140700	Light ice cream, creamsicle or dreamsicle (formerly ice milk)	3	85
13150000	Sherbet, all flavors	3	120
13160160	Fat free ice cream, no sugar added, flavors other than chocolate	3	120
13160400	Fat free ice cream, flavors other than chocolate	3	120
13161000	Milk dessert bar, frozen, made from lowfat milk	3	120
13161500	Milk dessert sandwich bar, frozen, made from lowfat milk	3	120
13161520	Milk dessert sandwich bar, frozen, with low-calorie sweetener, made from lowfat milk	3	120
13161600	Milk dessert bar, frozen, made from lowfat milk and low calorie sweetener	3	120
13161630	Light ice cream, bar or stick, with low-calorie sweetener, chocolate-coated (formerly ice milk)	3	120
63420100	Fruit juice bar, frozen, orange flavor	3	85
63420110	Fruit juice bar, frozen, flavor other than orange	3	85
63420200	Fruit juice bar, frozen, sweetened with low calorie sweetener, flavors other than orange	3	85
63430100	Sorbet, fruit, noncitrus flavor	3	120
63430110	Sorbet, fruit, citrus flavor	3	120
91611100	Ice pop, sweetened with low calorie sweetener	3	85

Gravies and Sauces

Food Code	Gravies and Sauces: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
27111050	Spaghetti sauce with beef or meat other than lamb or mutton, homemade-style*	3	125
28501010	Gravy, beef or meat, fat free*	3	60
28501110	Gravy, poultry, fat free*	3	60
74403010	Tomato sauce*	3	60
74403110	Tomato paste*	3	30
74404010	Spaghetti sauce, meatless*	3	125
74404020	Spaghetti sauce with vegetables, homemade-style*	3	125
74404030	Spaghetti sauce with meat, canned, no extra meat added*	3	125
74404060	Spaghetti sauce, meatless, fat free*	3	125
27111000	Beef with tomato-based sauce (mixture)	3	125
27111300	Mexican style beef stew, no potatoes, tomato-based sauce (mixture) (Carne guisada sin papas)	3	125
27111310	Mexican style beef stew, no potatoes, with chili peppers, tomato-based sauce (mixture) (Carne guisada con chile)	3	125

Food Code	Gravies and Sauces: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
27120100	Ham or pork with tomato-based sauce (mixture)	3	125
27120110	Sausage with tomato-based sauce (mixture)	3	125
27120130	Mexican style pork stew, no potatoes, tomato-based sauce (mixture) (cerdo guisado sin papas)	3	125
27120250	Frankfurters or hot dogs with tomato-based sauce (mixture)	3	125
27135110	Veal parmigiana	3	125
27136050	Venison/deer with tomato-based sauce (mixture)	3	125
27141000	Chicken or turkey cacciatore	3	125
27141030	Spaghetti sauce with poultry, home-made style	3	125
27141050	Stewed chicken with tomato-based sauce, Mexican style (mixture) (Pollo guisado con tomate)	3	125
27146300	Chicken or turkey parmigiana	3	125
27150110	Shrimp cocktail (shrimp with cocktail sauce)	3	125
27150310	Fish with tomato-based sauce (mixture)	3	125
27150330	Mussels with tomato-based sauce (mixture)	3	125
27150350	Sardines with tomato-based sauce (mixture)	3	125
27151040	Crabs in tomato-based sauce, Puerto Rican style (mixture) (Salmorejo de jueyes)	3	125
27162010	Meat with tomato-based sauce (mixture)	3	125
27162050	Spaghetti sauce with combination of meats, homemade-style	3	125
27162060	Spaghetti sauce with meat and vegetables, homemade-style	3	125
27211100	Beef stew with potatoes, tomato-based sauce (mixture)	3	125
27211110	Mexican style beef stew with potatoes, tomato-based sauce (mixture) (Carne guisada con papas)	3	125
27212100	Beef and noodles with tomato-based sauce (mixture)	3	125
27213100	Beef and rice with tomato-based sauce (mixture)	3	125
27213120	Porcupine balls with tomato-based sauce (mixture)	3	125
27214110	Meat loaf made with beef, with tomato-based sauce	3	125
27220120	Sausage and rice with tomato-based sauce (mixture)	3	125
27221150	Mexican style pork stew, with potatoes, tomato-based sauce (mixture) (cerdo guisado con papas)	3	125
27242400	Chicken or turkey and noodles, tomato-based sauce (mixture)	3	125
27243500	Chicken or turkey and rice with tomato-based sauce (mixture)	3	125
27250810	Fish and rice with tomato-based sauce	3	125
27250950	Shellfish mixture and noodles, tomato-based sauce (mixture)	3	125
27260100	Meat loaf made with beef and pork, with tomato-based sauce	3	125
27311310	Beef stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce	3	125
27311320	Beef stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce	3	125
27313210	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-	3	125

Food Code	Gravies and Sauces: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
	green leafy), tomato-based sauce (mixture)		
27313220	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)	3	125
27315210	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)	3	125
27315220	Beef, rice, and vegetables (excluding carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)	3	125
27320080	Sausage, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce	3	125
27320100	Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)	3	125
27320110	Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)	3	125
27320340	Pork, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)	3	125
27320350	Pork, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)	3	125
27330060	Lamb or mutton, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)	3	125
27330210	Lamb or mutton stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce	3	125
27330220	Lamb or mutton stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce	3	125
27336100	Venison/deer stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce	3	125
27341510	Chicken or turkey stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce	3	125
27341520	Chicken or turkey stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato- based sauce	3	125
27343510	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)	3	125
27343520	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)	3	125
27345510	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)	3	125
27345520	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)	3	125
27350310	Seafood stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-base sauce	3	125
27411100	Beef with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)	3	125
27411150	Beef rolls, stuffed with vegetables or meat mixture, tomato-based sauce	3	125
27411200	Beef with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)	3	125
27418310	Corned beef with tomato sauce and onion, Puerto Rican style (mixture)	3	125
27420410	Pork and vegetables (excluding carrots, broccoli, and dark- green leafy (no potatoes)), tomato-based sauce (mixture)	3	125
27420450	Sausage and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)	3	125
27420460	Sausage and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)	3	125
27450700	Fish and vegetables (including carrots, broccoli, and/or dark-green leafy	3	125

Food Code	Gravies and Sauces: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
	(no potatoes)), tomato-based sauce (mixture)		
27450710	Fish and vegetables (excluding carrots, broccoli, and dark- green leafy (no potatoes)), tomato-based sauce (mixture)	3	125
27510700	Meatball and spaghetti sauce submarine sandwich	3	125
58100600	Enchilada with chicken, tomato-based sauce	3	125
58100610	Enchilada with chicken and beans, tomato-based sauce	3	125
58100620	Enchilada with chicken, beans, and cheese, tomato- based sauce	3	125
58100630	Enchilada with chicken and cheese, no beans, tomato- based sauce	3	125
58101730	Taco or tostada with beans, cheese, meat, lettuce, tomato and salsa	3	125
58101800	Ground beef with tomato sauce and taco seasonings on a cornbread crust	3	125
58101820	Mexican casserole made with ground beef, beans, tomato sauce, cheese, taco seasonings, and corn chips	3	125
58101830	Mexican casserole made with ground beef, tomato sauce, cheese, taco seasonings, and corn chips	3	125
58106210	Pizza, cheese, NS as to type of crust	3	125
58106230	Pizza, cheese, thick crust	3	125
58106310	Pizza, cheese, with vegetables, NS as to type of crust	3	125
58106320	Pizza, cheese, with vegetables, thin crust	3	125
58106330	Pizza, cheese, with vegetables, thick crust	3	125
58106360	Pizza, cheese, with fruit, thick crust	3	125
58106510	Pizza with meat, NS as to type of crust	3	125
58106520	Pizza with meat, thin crust	3	125
58106530	Pizza with meat, thick crust	3	125
58106710	Pizza with meat and vegetables, NS as to type of crust	3	125
58106720	Pizza with meat and vegetables, thin crust	3	125
58106730	Pizza with meat and vegetables, thick crust	3	125
58106740	Pizza with meat and fruit, NS as to type of crust	3	125
58106750	Pizza with meat and fruit, thin crust	3	125
58106760	Pizza with meat and fruit, thick crust	3	125
58106820	Pizza with beans and vegetables, thin crust	3	125
58106830	Pizza with beans and vegetables, thick crust	3	125
58107030	Pizza, no cheese, NS as to type of crust	3	125
58107050	Pizza, no cheese, thin crust	3	125
58107100	Pizza, no cheese, thick crust	3	125
58108050	Pizza rolls	3	125
58116110	Meat turnover, Puerto Rican style (Pastelillo de carne; Empanadilla)	3	125
58126150	Turnover, meat- and cheese-filled, tomato-based sauce	3	125
58126300	Turnover, meat- and cheese-filled, tomato-based sauce, lower in fat	3	125

Food Code	Gravies and Sauces: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
58130011	Lasagna with meat	3	125
58130013	Lasagna with meat, canned	3	125
58130020	Lasagna with meat and spinach	3	125
58130140	Lasagna with chicken or turkey	3	125
58130310	Lasagna, meatless	3	125
58130320	Lasagna, meatless, with vegetables	3	125
58131110	Ravioli, NS as to filling, with tomato sauce	3	125
58131320	Ravioli, meat-filled, with tomato sauce or meat sauce	3	125
58131323	Ravioli, meat-filled, with tomato sauce or meat sauce, canned	3	125
58131520	Ravioli, cheese-filled, with tomato sauce	3	125
58131523	Ravioli, cheese-filled, with tomato sauce, canned	3	125
58131530	Ravioli, cheese-filled, with meat sauce	3	125
58131610	Ravioli, cheese and spinach filled, with tomato sauce	3	125
58132110	Spaghetti with tomato sauce, meatless	3	125
58132113	Pasta with tomato sauce and cheese, canned	3	125
58132310	Spaghetti with tomato sauce and meatballs or spaghetti with meat sauce or spaghetti with meat sauce and meatballs	3	125
58132313	Pasta with tomato sauce and meat or meatballs, canned	3	140
58132340	Spaghetti with tomato sauce and vegetables	3	125
58132710	Spaghetti with tomato sauce and frankfurters or hot dogs	3	125
58132713	Pasta with tomato sauce and frankfurters or hot dogs, canned	3	125
58132810	Spaghetti with red clam sauce	3	125
58132910	Spaghetti with tomato sauce and chicken or turkey	3	125
58133120	Manicotti, cheese-filled, with tomato sauce, meatless	3	125
58133130	Manicotti, cheese-filled, with meat sauce	3	125
58133140	Manicotti, vegetable- and cheese-filled, with tomato sauce, meatless	3	125
58134120	Stuffed shells, cheese-filled, with tomato sauce, meatless	3	125
58134130	Stuffed shells, cheese-filled, with meat sauce	3	125
58134210	Stuffed shells, with chicken, with tomato sauce	3	125
58134610	Tortellini, meat-filled, with tomato sauce	3	125
58134620	Tortellini, cheese-filled, meatless, with tomato sauce	3	125
58134623	Tortellini, cheese-filled, meatless, with tomato sauce, canned	3	125
58134710	Tortellini, spinach-filled, with tomato sauce	3	125
58145140	Macaroni or noodles with cheese and tomato	3	125
58146100	Pasta with tomato sauce, meatless	3	125
58146110	Pasta with meat sauce	3	125
58146120	Pasta with cheese and meat sauce	3	125

Food Code	Gravies and Sauces: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
58146150	Pasta with cheese and tomato sauce, meatless	3	125
58160220	Rice with vegetables, tomato-based sauce (mixture)	3	125
58161300	White rice with tomato sauce	3	125
58161310	Rice, brown, with tomato sauce	3	125
75306010	Eggplant in tomato sauce, cooked, fat not added in cooking	3	110
75316010	Zucchini with tomato sauce, cooked, fat not added in cooking	3	110
75412070	Eggplant with cheese and tomato sauce	3	125
75418030	Squash, summer, casserole, with rice and tomato sauce	3	125

*100% of the foods marked with an asterisk were included in the analysis. Only the tomato sauce portion of the remaining foods was included in the analysis.

Meal Replacements

Food Code	Meal Replacements: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
11613000	Instant breakfast, powder, sweetened with low calorie sweetener, milk added	3	240
11623000	Meal supplement or replacement, commercially prepared, ready-to-drink	3	240
11830550	Milk beverage, powder, with nonfat dry milk and low calorie sweetener, dry mix, not reconstituted, flavors other than chocolate	3	34
11830810	Instant breakfast, powder, sweetened with low calorie sweetener, not reconstituted	3	34
11830900	Protein supplement, milk-based, powdered, not reconstituted	3	30
11830940	Meal replacement, high protein, milk based, fruit juice mixable formula, powdered, not reconstituted	3	30
11830970	Meal replacement, protein type, milk-based, powdered, not reconstituted	3	30
11830990	Nutrient supplement, milk-based, powdered, not reconstituted	3	30

Pasta and Grain Products

Food Code	Pasta and Grain Products: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
56102000	Macaroni, whole wheat, cooked, NS as to fat added in cooking	3	140
56102010	Macaroni, whole wheat, cooked, fat not added in cooking	3	140
56102020	Macaroni, whole wheat, cooked, fat added in cooking	3	140
56104010	Macaroni, cooked, vegetable, fat not added in cooking	3	140
56104020	Macaroni, cooked, vegetable, fat added in cooking	3	140

Food Code	Pasta and Grain Products: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
56113010	Noodles, cooked, whole wheat, fat not added in cooking	3	140
56114000	Noodles, cooked, spinach, fat not added in cooking	3	140
56114020	Noodles, cooked, spinach, fat added in cooking	3	140
56132990	Spaghetti, cooked, whole wheat, NS as to fat added in cooking	3	140
56133000	Spaghetti, cooked, whole wheat, fat not added in cooking	3	140
56133010	Spaghetti, cooked, whole wheat, fat added in cooking	3	140
56205510	Rice, brown, cooked, regular, fat added in cooking	3	140
56205540	Rice, brown, cooked, instant, fat not added in cooking	3	140
56205550	Rice, brown, cooked, instant, fat added in cooking	3	140
58163310	Flavored rice mixture	3	140
58163330	Flavored rice mixture with cheese	3	140
58163360	Flavored rice, brown and wild	3	140
58163380	Flavored rice and pasta mixture	3	140
58163410	Spanish rice	3	240
58163510	Rice dressing	3	240
58163610	Rice-vegetable medley	3	240
58164110	Rice with raisins	3	240
58132350	Spaghetti with tomato sauce, meatless, whole wheat noodles*	3	240
58132360	Spaghetti with tomato sauce and meatballs, whole wheat noodles or spaghetti with meat sauce, whole wheat noodles or spaghetti with meat sauce and meatballs, whole wheat noodles*	3	240
58132450	Spaghetti with tomato sauce, meatless, made with spinach noodles*	3	240
58132460	Spaghetti with tomato sauce and meatballs made with spinach noodles, or spaghetti with meat sauce made with spinach noodles, or spaghetti with meat sauce and meatballs made with spinach noodles*	3	240
58146310	Pasta, whole wheat, with tomato sauce, meatless*	3	240

*100% of these dishes contain resistant dextrin (covering both the gravies and sauces as well as the pasta portion)

Prepared Meals and Soups

Food Code	Prepared Meals and Soups: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
28110150	Beef with vegetable (diet frozen meal)	3	240
28110390	Salisbury steak, potatoes, vegetable, dessert (diet frozen meal)	3	240
28110660	Meatballs, Swedish, in gravy, with noodles (diet frozen meal)	3	240
28113110	Salisbury steak, baked, with tomato sauce, vegetable (diet frozen meal)	3	240
28120310	Pork with rice, vegetable, in soy-based sauce (diet frozen meal)	3	240
28141201	Teriyaki chicken with rice and vegetable (diet frozen meal)	3	240

Food Code	Prepared Meals and Soups: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
28141250	Chicken with rice-vegetable mixture (diet frozen meal)	3	240
28141300	Chicken with rice and vegetable, reduced fat and sodium (diet frozen meal)	3	240
28141610	Chicken and vegetables in cream or white sauce (diet frozen meal)	3	240
28141650	Chicken and vegetables au gratin with rice-vegetable mixture (diet frozen entree)	3	240
28143020	Chicken and vegetable entree with rice, Oriental (diet frozen meal)	3	240
28143030	Chicken and vegetable entree, oriental (diet frozen meal)	3	240
28143040	Chicken chow mein with rice (diet frozen meal)	3	240
28143080	Chicken with noodles and cheese sauce (diet frozen meal)	3	240
28143110	Chicken cacciatore with noodles (diet frozen meal)	3	240
28143150	Chicken and vegetable entree with noodles (diet frozen meal)	3	240
28143180	Chicken in butter sauce with potatoes and vegetable (diet frozen meal)	3	240
28143210	Chicken in orange sauce with almond rice (diet frozen meal)	3	240
28143220	Chicken in barbecue sauce, with rice, vegetable and dessert, reduced fat and sodium (diet frozen meal)	3	240
28145100	Turkey with dressing, gravy, vegetable and fruit (diet frozen meal)	3	240
28145110	Turkey with vegetable, stuffing (diet frozen meal)	3	240
28150210	Haddock with chopped spinach (diet frozen meal)	3	240
28154010	Shrimp and vegetables in sauce with noodles (diet frozen meal)	3	240
28160710	Stuffed cabbage, with meat and tomato sauce (diet frozen meal)	3	240
28340170	Chicken broth, canned, low sodium	3	245
28345040	Chicken or turkey soup, cream of, canned, reduced sodium, undiluted	3	245
28355140	Clam chowder, New England, canned, reduced sodium, ready-to-serve	3	245
41440000	Textured vegetable protein, dry	3	30
41602070	Split pea soup, canned, reduced sodium, prepared with water or ready-to-serve	3	245
41602090	Split pea and ham soup, canned, reduced sodium, prepared with water or ready-to-serve	3	245
41810200	Bacon strip, meatless	3	15
41810250	Bacon bits, meatless	3	7
41810400	Breakfast link, pattie, or slice, meatless	3	55
41810610	Chicken, meatless, breaded, fried	3	140
41811400	Frankfurter or hot dog, meatless	3	55
41811600	Luncheon slice, meatless-beef, chicken, salami or turkey	3	55
41811800	Meatball, meatless	3	55
41811890	Vegetarian burger or patty, meatless, no bun	3	140
41811900	Soyburger, meatless, no bun	3	140
41811910	Vegetable burger or patty, meatless, no bun	3	140
41812000	Sandwich spread, meat substitute type	3	55

Food Code	Prepared Meals and Soups: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
41812450	Vegetarian chili (made with meat substitute)	3	240
41812600	Vegetarian, fillet	3	140
41812850	Vegetarian stroganoff (made with meat substitute)	3	240
41812900	Vegetarian meat loaf or patties (meat loaf made with meat substitute)	3	55
58106220	Pizza, cheese, thin crust	3	140
58106780	Pizza with meat and vegetables, lowfat, thin crust	3	140
58301020	Lasagna with cheese and sauce (diet frozen meal)	3	240
58301030	Veal lasagna (diet frozen meal)	3	240
58301050	Lasagna with cheese and meat sauce (diet frozen meal)	3	240
58301150	Zucchini lasagna (diet frozen meal)	3	240
58302000	Macaroni and cheese (diet frozen meal)	3	240
58302050	Beef and noodles with meat sauce and cheese (diet frozen meal)	3	240
58302080	Noodles with vegetables in tomato-based sauce (diet frozen meal)	3	240
58304050	Spaghetti with meat and mushroom sauce (diet frozen meal)	3	240
58304060	Spaghetti with meat sauce (diet frozen meal)	3	240
58304200	Ravioli, cheese-filled, with tomato sauce (diet frozen meal)	3	240
58304250	Manicotti, cheese-filled, with tomato sauce (diet frozen meal)	3	240
58304400	Linguini with vegetables and seafood in white wine sauce (diet frozen meal)	3	240
58305250	Pasta with vegetable and cheese sauce (diet frozen meal)	3	240
58306100	Chicken enchilada (diet frozen meal)	3	240
58400100	Noodle soup, NFS	3	245
58400200	Rice soup, NFS	3	245
58401010	Barley soup	3	245
58403030	Chicken noodle soup, canned, low sodium, ready-to-serve	3	245
58403060	Chicken noodle soup, canned, reduced sodium, ready-to-serve	3	245
58404040	Chicken rice soup, canned, reduced sodium, prepared with water or ready-to-serve	3	245
58407010	Instant soup, noodle	3	245
58407030	Soup, mostly noodles	3	245
58407040	Instant soup, rice	3	245
58407050	Instant soup, noodle with egg, shrimp or chicken	3	245
59003000	Meat substitute, cereal- and vegetable protein-based, fried	3	85
74602100	Tomato soup, canned, low sodium, ready-to-serve	3	245
74602200	Tomato soup, canned, reduced sodium, prepared with water	3	245
74602300	Tomato soup, canned, reduced sodium, prepared with milk	3	245
75607050	Mushroom soup, cream of, low sodium, prepared with water	3	245
75607140	Mushroom soup, cream of, canned, reduced sodium, prepared with water	3	245

Food Code	Prepared Meals and Soups: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
75609050	Pea soup, canned, low sodium, prepared with water	3	245
75649030	Vegetable soup, canned, low sodium, prepared with water or ready-to-serve	3	245
75649070	Vegetable soup, made from dry mix, low sodium	3	245
75650990	Minestrone soup, canned, reduced sodium, ready-to-serve	3	245
75651150	Vegetable noodle soup, canned, reduced sodium, prepared with water or ready-to-serve	3	245

Processed Fruits

Food Code	Processed Fruits: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
62101000	Fruit, dried, NFS (assume uncooked)	3	40
62101050	Fruit mixture, dried (mixture includes three or more of the following: apples, apricots, dates, papaya, peaches, pears, pineapples, prunes, raisins)	3	40
62101100	Apple, dried, uncooked	3	40
62101200	Apple, dried, cooked, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener	3	140
62101300	Apple chips	3	30
62104100	Apricot, dried, uncooked	3	40
62104200	Apricot, dried, cooked, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener	3	140
62107200	Banana chips	3	30
62108100	Currants, dried	3	40
62109100	Cranberries, dried	3	40
62110100	Date	3	40
62113100	Fig, dried, uncooked	3	40
62114050	Mango, dried	3	40
62114110	Papaya, dried	3	40
62116100	Peach, dried, uncooked	3	40
62119100	Pear, dried, uncooked	3	40
62119230	Pear, dried, cooked, with sugar	3	140
62120100	Pineapple, dried	3	40
62122100	Prune, dried, uncooked	3	40
62122200	Prune, dried, cooked, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener	3	140
62125100	Raisins	3	40
62125110	Raisins, cooked	3	140
62126000	Tamarind pulp, dried, sweetened ("Pulpitas")	3	40
63101110	Applesauce, stewed apples, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener	3	70
63101120	Applesauce, stewed apples, unsweetened	3	70
63101130	Applesauce, stewed apples, with sugar	3	70
63101140	Applesauce, stewed apples, sweetened with low calorie sweetener	3	70
63101150	Applesauce with other fruits	3	70
63101320	Apple, baked, unsweetened	3	140
63135110	Peach, cooked or canned, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener	3	140
63135120	Peach, cooked or canned, unsweetened, water pack	3	140
63135130	Peach, cooked or canned, in heavy syrup	3	140

Food Code	Processed Fruits: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
63135140	Peach, cooked or canned, in light or medium syrup	3	140
63135150	Peach, cooked or canned, drained solids	3	140
63135170	Peach, cooked or canned, juice pack	3	140
63137110	Pear, cooked or canned, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener	3	140
63137130	Pear, cooked or canned, in heavy syrup	3	140
63137140	Pear, cooked or canned, in light syrup	3	140
63137150	Pear, cooked or canned, drained solids	3	140
63137170	Pear, cooked or canned, juice pack	3	140
63141110	Pineapple, cooked or canned, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener	3	140
63141130	Pineapple, cooked or canned, in heavy syrup	3	140
63141140	Pineapple, cooked or canned, in light syrup	3	140
63141150	Pineapple, cooked or canned, drained solids	3	140
63141170	Pineapple, cooked or canned, juice pack	3	140
63207000	Cranberries, NS as to raw, cooked, or canned	3	55
63207110	Cranberries, cooked or canned	3	55

Shelf Stable Desserts

Food Code	Shelf Stable Desserts: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
13200110	Pudding, NFS	3	147
13210250	Pudding, chocolate, ready-to-eat, low calorie, containing artificial sweetener, NS as to from dry mix or canned	3	147
13210290	Pudding, flavors other than chocolate, ready-to-eat, low calorie, containing artificial sweetener, NS as to from dry mix or canned	3	147
13220210	Pudding, flavors other than chocolate, prepared from dry mix, low calorie, containing artificial sweetener, milk added	3	147
13220220	Pudding, chocolate, prepared from dry mix, low calorie, containing artificial sweetener, milk added	3	147
13220230	Pudding, canned, chocolate, reduced fat	3	147
13220235	Pudding, canned, chocolate, fat free	3	147
13220240	Pudding, canned, flavors other than chocolate, reduced fat	3	147
13220245	Pudding, canned, flavors other than chocolate, fat free	3	147
13230120	Pudding, canned, low calorie, containing artificial sweetener, flavors other than chocolate	3	147
13230140	Pudding, canned, low calorie, containing artificial sweetener, chocolate	3	147
13230510	Pudding, canned, tapioca, fat free	3	147
91501010	Gelatin dessert	3	120

Food Code	Shelf Stable Desserts: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
91501015	Gelatin snacks	3	120
91511010	Gelatin dessert, dietetic, sweetened with low calorie sweetener	3	120
91511020	Gelatin dessert, dietetic, with fruit, sweetened with low calorie sweetener	3	120
91511030	Gelatin dessert, dietetic, with whipped topping, sweetened with low calorie sweetener	3	120
91511070	Gelatin dessert, dietetic, with fruit and sour cream, sweetened with low calorie sweetener	3	120
91511100	Gelatin salad, dietetic, with vegetables, sweetened with low calorie sweetener	3	120

Snacks and Crackers

Food Code	Snacks and Crackers: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
41205050	Bean dip, made with refried beans	3	30
41205070	Hummus	3	30
54001000	Crackers, NS as to sweet or nonsweet	3	30
54101010	Cracker, animal	3	30
54102100	Crackers, graham, lowfat	3	30
54102110	Crackers, graham, fat free	3	30
54201010	Crackers, matzo, low sodium	3	30
54202010	Crackers, saltine, low sodium	3	30
54202050	Crackers, saltine, fat free, low sodium	3	30
54203010	Crackers, toast thins (rye, wheat, white flour), low sodium	3	30
54204010	Cracker, 100% whole wheat, low sodium	3	30
54205010	Cracker, snack, low sodium	3	30
54205030	Cracker, cheese, low sodium	3	30
54205100	Cracker, snack, lowfat, low sodium	3	30
54210010	Cracker, multigrain, salt free	3	30
54301100	Cracker, snack, reduced fat	3	30
54301200	Cracker, snack, fat free	3	30
54304100	Cracker, cheese, reduced fat	3	30
54304500	Cracker, high fiber, no added fat	3	30
54305000	Crispbread, wheat, no added fat	3	30
54305500	Crispbread, wheat or rye, extra crispy	3	30
54307000	Crackers, matzo	3	30
54318500	Rice cake, cracker-type	3	30
54319000	Crackers, rice	3	30

Food Code	Snacks and Crackers: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
54319010	Puffed rice cake	3	30
54319020	Popcorn cake	3	30
54322000	Crispbread, rye, no added fat	3	30
54325000	Crackers, saltine	3	30
54325050	Crackers, saltine, whole wheat	3	30
54328110	Cracker, sandwich-type, peanut butter filled, reduced fat	3	30
54336000	Crackers, water biscuits	3	30
54337000	Cracker, 100% whole wheat	3	30
54337050	Cracker, 100% whole wheat, reduced fat	3	30
54338000	Crackers, wheat	3	30
54338100	Crackers, wheat, reduced fat	3	30
54401090	Salty snacks, corn or cornmeal base, corn chips, corn-cheese chips, unsalted	3	30
54401100	Salty snacks, corn or cornmeal base, tortilla chips, light (baked with less oil)	3	30
54401120	Salty snacks, corn or cornmeal base, tortilla chips, fat free, made with Olean	3	30
54401150	Salty snacks, corn or cornmeal base, tortilla chips, lowfat, baked without fat	3	30
54401170	Salty snacks, corn or cornmeal base, tortilla chips, lowfat, baked without fat, unsalted	3	30
54401210	Salty snacks, corn based puffs and twists, cheese puffs and twists, lowfat	3	30
54402080	Salty snacks, corn or cornmeal base, tortilla chips, unsalted	3	30
54402600	Salty snacks, multigrain, chips	3	30
54408000	Pretzels, NFS	3	30
54408010	Pretzels, hard	3	30
54408030	Pretzel, hard, unsalted	3	30
54408200	Pretzel, hard, chocolate-coated	3	30
54408250	Pretzel, yogurt-covered	3	30
54408300	Pretzels, cheese-filled	3	30
54420010	Multigrain mixture, pretzels, cereal and/or crackers, nuts	3	30
54420100	Oriental party mix, with peanuts, sesame sticks, chili rice crackers and fried green peas	3	30
54420200	Multigrain mixture, bread sticks, sesame nuggets, pretzels, rye chips	3	30
63408010	Guacamole with tomatoes	3	30
63408200	Guacamole with tomatoes and chili peppers	3	30
63409010	Guacamole, NFS	3	30
63409020	Chutney	3	30
74402100	Salsa, NFS	3	30
74402110	Salsa, red, uncooked	3	30

Food Code	Snacks and Crackers: NHANES 2003-06 Food Description	Proposed Use Rate (g/serving)	21CFR101.12 Serving size (RACC)
74402150	Salsa, red, cooked, not homemade	3	30
75412030	Eggplant dip	3	30
58100360	Chilaquiles, tortilla casserole with salsa, cheese, and egg*	3	30
58100370	Chilaquiles, tortilla casserole with salsa and cheese, no egg*	3	30
58100400	Enchilada with beef, no beans*	3	30
58100520	Enchilada with beef, beans, and cheese*	3	30
58100530	Enchilada with beef and cheese, no beans*	3	30
58100710	Enchilada with beans, meatless*	3	30
58100720	Enchilada with beans and cheese, meatless*	3	30
58100800	Enchilada with cheese, meatless, no beans*	3	30
58101310	Taco or tostada with beef, lettuce, tomato and salsa*	3	30
58101320	Taco or tostada with beef, cheese, lettuce, tomato and salsa*	3	30
58101510	Taco or tostada with chicken or turkey, lettuce, tomato and salsa**	3	30
58101520	Taco or tostada with chicken, cheese, lettuce, tomato and salsa*	3	30
58101530	Soft taco with beef, cheese, lettuce, tomato and salsa*	3	30
58101540	Taco or tostada with fish, lettuce, tomato, salsa*	3	30
58101710	Taco or tostada with beans, meatless, with lettuce, tomato and salsa*	3	30
58101720	Taco or tostada with beans and cheese, meatless, with lettuce, tomato and salsa*	3	30
58104290	Chalupa with beef, cheese, lettuce, tomato and salsa*	3	30
58104340	Chalupa with chicken, cheese, lettuce, tomato and salsa*	3	30

*Resistant dextrin was applied to only the salsa portion of the mixed dishes and the serving size of salsa (30g) was used to estimate the EDI of resistant dextrin rather than the serving size of the mixed dish (approximately 140g).

SUBMISSION END